CMS-4064-IFC-1 **Medicare Program; Changes to the Medicare Claims Appeals Procedures**

Submitter : Ms. kathy thurman **Date & Time:** 03/11/2005

Organization : Ms. kathy thurman

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

IF this recommendation goes through Most if not all your mental health facilities will close. Look at Northwest Arkansas and all the problems that have arisen from the closing of inpatient psych facilities. I had worked as a psych nurse for 12 years. Working with children through geriatric ages. Now alot of our population with mental health issues are in county jails,juvenille facilities or being monitored in cardic or ICU units of hospitals. More and more staff are being injured and the risk to other patients is increased. Also the cost to the hospital rises when you have to hire staff to stay one on one with dangerous or suicidal patients on a hospital floor not set-up for this specific type of patients. School Teachers,Nurses and other staff are also dealing with more and more mental health issues in the school due to lack of facilities as well as trained staff to work with children and adolescents. Mental Health benefits are usually 50% payment with private insurance and if goverment lowers there reembursment the private compainies will be inclined to follow suit. The General Public Opinion is Don't have mental health issues no one seems to care and the for profit hospitals don't want to loose money. Most psychiatric problems are due to hereditary and enviormental situations. The Old Adage Pull Your Self Up By The Boot Straps Just Don't Work.

CMS-4064-IFC-2 **Medicare Program; Changes to the Medicare Claims Appeals Procedures**

Submitter : **Ms. Janice Erickson** **Date & Time:** **03/14/2005**

Organization : **Aging & Disability Resource Center**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

In reviewing the proposed changes to the Medicare Appeals process. I am against eliminating the in-person fair hearing for Part B services. This step can be a fairly informal & non-threatening way for the Medicare beneficiary to make a statement regarding their case. I am also against making it more difficult for an in-person Administrative hearing. Individuals should have a right to appear with an advocate or attorney without further barriers.

CMS-4064-IFC-5 **Medicare Program; Changes to the Medicare Claims Appeals Procedures**

Submitter : Mrs. Lisa DiSalvo **Date & Time:** 04/25/2005

Organization : Pharmaceutical Buyers Inc

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-5-Attach-1.DOC

Reply CMS-1325-P

Submitter : Mr. Tristan North **Date:** 04/28/2005

Organization : American Ambulance Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-6-Attach-1.DOC

AMERICAN AMBULANCE ASSOCIATION

American Ambulance Association
8201 Greensboro Drive, Suite 300
McLean, Virginia 22102
Phone: (703) 610-9018
Fax: (703) 610-9005
Website: www.the-aaa.org

"The American Ambulance Association promotes health care policies that ensure excellence in the ambulance service industry and provides research, education, and communications programs to enable members to effectively address the needs of the communities they serve."

April 28, 2005

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

Re: Comments on CMS-4064-IFC—Medicare Claims Appeal Procedures

Dear Sir or Madam:

The American Ambulance Association ("AAA" or "the Association") appreciates the opportunity to comment on the proposed regulation that would implement statutory changes to the Medicare claims appeal procedures. The Medicare claims appeals process has been a concern of the Association for a number of years and we welcome the changes that are designed to expedite the handling of appeals and provide additional assurances of fairness and independence in the process. We appreciate the time and effort that CMS has spent in developing the regulations to implement these important changes.

The American Ambulance Association represents ambulance services across the United States that participate in serving more than 75% of the U.S. population with emergency and non-emergency care and medical transportation services. The AAA was formed in response to the need for improvements in medical transportation and emergency medical services. The Association services as a voice and clearinghouse for ambulance services across the nation. The Association views prehospital care not only as a public service, but also as an essential part of the total public health care system.

The Association also represents the interests of its members in assuring that they receive appropriate reimbursement for services provided to Medicare and Medicaid patients and that disputes over that reimbursement are resolved in a timely fashion through a fair and impartial process. We believe the interim final rule could help to achieve these objectives. However, a number of changes to the interim final rule are necessary to level the playing field and to assure that providers and suppliers have a fair opportunity to present their appeals and receive a fully considered and impartial decision. The necessary changes are outlined below.

Reconsiderations. Section 405.966(a)(2) of the rule, implementing section 1869(b)(3) of the statute, provides that if evidence is not submitted by a provider or supplier at the

qualified independent contractor ("QIC") level, it cannot be submitted during a subsequent appeal without a finding of good cause. Ambulance suppliers, through no fault of their own, are often unable to obtain a record or other documentation that may be necessary to prove their case at the reconsideration level. Lack of cooperation by a facility treating the patient or refusal of a physician to supply a letter documenting the order for an ambulance to be called are examples of such inability to produce needed evidence. The regulation needs to make clear that such occurrences, totally outside the supplier's control, would constitute good cause for such documentation to be considered at a subsequent appeal level.

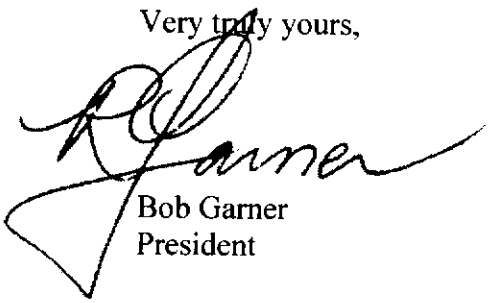
ALJ Hearings. Section 405.1010(d) provides the if CMS or a contractor participates in an ALJ hearing, they cannot be called as a witness. We do not understand the purpose of this provision or how it can lead to a more complete examination of all the issues, which we understand to be CMS' objective in allowing CMS or a contractor to participate in a hearing in the first place. It is frequently necessary for a supplier to call a contractor representative, or even CMS, as a witness in order to establish the grounds on which they based their action on a claim or determination. The fact that CMS or the contractor has been made party to the hearing is irrelevant to the usefulness of such testimony. CMS or its contractors should not be able to immunize themselves against being called as a witness simply by deciding to participate as a party to the hearing. We believe you should delete this provision of the rule.

Section 405.1036(f) allows subpoenas to be requested for an ALJ hearing, but states that they must be requested within 10 days of the notice of the hearing. Furthermore, a subpoena may be requested only after discovery is sought, a motion to compel is filed and granted, and the subpoenaed party does not supply the requested records. In light of the requirement that a party must exhaust these other efforts to obtain the records before seeking a subpoena, it is unreasonable to require that the request for a subpoena be filed within 10 days of the notice of hearing. The provision should be amended to require only that a subpoena request be filed before the decision of the ALJ. Alternatively, a party requesting a subpoena should be allowed a reasonable amount of time, after he has exhausted all other required efforts to obtain the records, to file the request for a subpoena.

Conclusion. The above comments all reflect our overriding concern that the rules governing these appeals not erect unnecessary and unfair barriers to the presentation of a provider or supplier's case at the various hearing levels. The primary purpose of the rules should be to assure that a complete picture of the facts and circumstances is presented to the hearing officer and that the government or its agent should be required to the fullest extent to ensure that the record is complete. Unfortunately, as explained above, the rules set forth in the interim final regulation too often inject adversarial procedures that may stand in the way of developing a full and accurate record upon which a decision can be based. We urge you to examine these issues with a view toward what should be our common goal—adjudicating claims on the basis of a true and accurate set of facts.

We appreciate the opportunity to submit these comments. Please let us know if we can provide any additional information or assistance.

Very truly yours,



Bob Garner
President

CMS-4064-IFC-7 **Medicare Program; Changes to the Medicare Claims Appeals Procedures**

Submitter : Mr. Dean Lampe **Date & Time:** 05/03/2005

Organization : North Dakota EMS Association

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-7-Attach-1.PDF

May 3, 2005

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

Re: Comments on CMS-4064-IFC—Medicare Claims Appeal Procedures

Dear Sir or Madam:

The North Dakota EMS Association ("NDEMSA" or "the Association") appreciates the opportunity to comment on the proposed regulation that would implement statutory changes to the Medicare claims appeal procedures. The Medicare claims appeals process has been a concern of the Association for a number of years and we welcome the changes that are designed to expedite the handling of appeals and provide additional assurances of fairness and independence in the process. We appreciate the time and effort that CMS has spent in developing the regulations to implement these important changes.

The NDEMSA represents ambulance services across North Dakota that participate in serving all of the State's population with emergency and non-emergency care and medical transportation services. The NDEMSA was formed in response to the need for improvements in medical transportation and emergency medical services. The Association services as a voice and clearinghouse for ambulance services and EMT's in North Dakota. The Association views pre-hospital care not only as a public service, but also as an essential part of the total public health care system.

The Association also represents the interests of its members in assuring that they receive appropriate reimbursement for services provided to Medicare and Medicaid patients and that disputes over that reimbursement are resolved in a timely fashion through a fair and impartial process. We believe the interim final rule could help to achieve these objectives. However, a number of changes to the interim final rule are necessary to level the playing field and to assure that providers and suppliers have a fair opportunity to present their appeals and receive a fully considered and impartial decision. The necessary changes are outlined below.

Reconsiderations. Section 405.966(a)(2) of the rule, implementing section 1869(b)(3) of the statute, provides that if evidence is not submitted by a provider or supplier at the qualified independent contractor ("QIC") level, it cannot be submitted during a subsequent appeal without a finding of good cause. Ambulance suppliers, through no fault of their own, are often unable to obtain a record or other documentation that may be necessary to prove their case at the

reconsideration level. Lack of cooperation by a facility treating the patient or refusal of a physician to supply a letter documenting the order for an ambulance to be called are examples of such inability to produce needed evidence. The regulation needs to make clear that such occurrences, totally outside the supplier's control, would constitute good cause for such documentation to be considered at a subsequent appeal level.

ALJ Hearings. Section 405.1010(d) provides that if CMS or a contractor participates in an ALJ hearing, they cannot be called as a witness. We do not understand the purpose of this provision or how it can lead to a more complete examination of all the issues, which we understand to be CMS' objective in allowing CMS or a contractor to participate in a hearing in the first place. It is frequently necessary for a supplier to call a contractor representative, or even CMS, as a witness in order to establish the grounds on which they based their action on a claim or determination. The fact that CMS or the contractor has been made party to the hearing is irrelevant to the usefulness of such testimony. CMS or its contractors should not be able to immunize themselves against being called as a witness simply by deciding to participate as a party to the hearing. We believe you should delete this provision of the rule.

Section 405.1036(f) allows subpoenas to be requested for an ALJ hearing, but states that they must be requested within 10 days of the notice of the hearing. Furthermore, a subpoena may be requested only after discovery is sought, a motion to compel is filed and granted, and the subpoenaed party does not supply the requested records. In light of the requirement that a party must exhaust these other efforts to obtain the records before seeking a subpoena, it is unreasonable to require that the request for a subpoena be filed within 10 days of the notice of hearing. The provision should be amended to require only that a subpoena request be filed before the decision of the ALJ. Alternatively, a party requesting a subpoena should be allowed a reasonable amount of time, after he has exhausted all other required efforts to obtain the records, to file the request for a subpoena.

Conclusion. The above comments all reflect our overriding concern that the rules governing these appeals not erect unnecessary and unfair barriers to the presentation of a provider or supplier's case at the various hearing levels. The primary purpose of the rules should be to assure that a complete picture of the facts and circumstances is presented to the hearing officer and that the government or its agent should be required to the fullest extent to ensure that the record is complete. Unfortunately, as explained above, the rules set forth in the interim final regulation too often inject adversarial procedures that may stand in the way of developing a full and accurate record upon which a decision can be based. We urge you to examine these issues with a view toward what should be our common goal—adjudicating claims on the basis of a true and accurate set of facts.

We appreciate the opportunity to submit these comments. Please let us know if we can provide any additional information or assistance.

Very truly yours,

Dean Lampe,
Executive Director

CMS-4064-IFC-8 **Medicare Program; Changes to the Medicare Claims Appeals Procedures**

Submitter : **Date & Time:** **05/03/2005**

Organization : **UNITED GOVERNMENT SERVICES**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-4064-IFC-8-Attach-1.DOC

Federal Register Interim Final Rule
Published March 8, 2005
UGS, LLC. Comments – Reference File Code CMS-4064-IFC
May 2, 2005

Appeal Rights – Basis and Scope, etc.

1. 405.902, pg. 11473 – UGS is unclear what the difference is between an appointed representative and an assignee for appeal purposes. Please include an example of an assignee and explain how this differs from the appointment of representative.

2. 405.904, pg. 11474 – This section indicates the SSA makes an initial determination for Medicare entitlement. It further states that the beneficiary who is dissatisfied with the determination may file an appeal request with the SSA. Our understanding is that the claim is rejected if CWF shows no Medicare entitlement. This information is shown on an MSN. The back of the MSN instructs the beneficiary to file an appeal with the contractor that processed the claim. Will there be changes to the MSN that coincide with the instructions in this section so the beneficiary is aware that the appeal should be filed with the SSA & not the Medicare contractor that processes the claim & produces the MSN?

3. 405.910, pg. 11475 – When will there be a new CMS Appointment of Representative form given the comments on pg. 11430, 1st column, 1st full paragraph indicate it will be revised?

Initial Determinations

1. 405.924(a)(1) & (4), pg. 11477 - These sections indicate the SSA makes an initial determination for Medicare entitlement. Our understanding is that the claim is rejected if CWF shows no Medicare entitlement. This information is shown on an MSN. If this is an initial determination, why would it not be appealed through the Medicare Appeal process rather than the SSA as indicated in 405.904?

Redeterminations

2. 405.944(b), pg. 11479 – This section indicates that the request for redetermination should be on a standard CMS form. When will there be a standardized redetermination request form?

3. 405.952(b)(4)(i), pg. 11480 – This section discusses that if there is an appeal in process and the beneficiary dies, the contractor can dismiss the case if the surviving spouse does not have financial interest in the case. The question is not directly about this section. Rather, we request that there be clarification of the following related issue. We have received appeal requests from surviving family members for claims that were denied, beneficiary liable after the beneficiary has died. Our

understanding of the IOM 100-4, Ch. 29, Section 60.5.10 is that a person appealing a denial for a deceased beneficiary must submit legal proof (i.e. – will or probate court document) showing he has the right to do so. In response to our request for this documentation, some requesters have informed us that there is no will and they are unable to obtain a probate court document because there are no assets. Thus, we have dismissed the appeal. Though I have explained to the family member that this is needed due to HIPAA, the family member asked what privacy needs to be protected as the person is dead. The family member also stated she was with the beneficiary when she was dying, so there is nothing that she does not know. It seems that when the beneficiary (now deceased, so the estate) is liable for the denied services, the surviving person should be able to submit an appeal request without any legal proof. We respectfully request that this issue be considered and addressed in the CFR.

ALJ Hearings

1. 405.1020(c), Pg. 11488 – This section indicates that the ALJ will send a notice of hearing to the contractor that issued the initial determination. Though we appreciate the opportunity for a contractor to be a participant or party, we believe that receiving ALJ notices of hearing for every case may be cumbersome. Our understanding is that the only action necessary by or communication about cases that go to the ALJ after the QIC reconsideration the AC receives is for purposes of effectuation. If the AC is not invited to be a participant or party to the hearing, it does not seem necessary or efficient for the ALJ to send notice of hearing for that case to the AC. If the AC's will be required to waive their right to appear at each hearing (405.1020(d)) this would be time-consuming and costly. Perhaps this could be changed to indicate the ALJ will send a notice of hearing to the AC (that processed the initial determination) when the ALJ requests that the AC be a party or participant.

Submitter : **Mr. Jonathan Morse** **Date: 05/06/2005**

Organization : **American Physical Therapy Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment. We have also submitted written comments by mail.

CMS-4064-IFC-9-Attach-1.DOC

May 6, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Changes to the Medicare Claims Appeal Procedures published by the Center for Medicare and Medicaid Services (CMS) in the Federal Register on March 8, 2005. The purpose of this document is to submit comments on behalf of the American Physical Therapy Association (APTA) in response to the Interim Final Rule. The APTA is a national organization representing over 67,000 physical therapists, physical therapist assistants, and students of physical therapy. We commend CMS on implementing these changes which will significantly improve the appeals process for providers and beneficiaries. We have three areas of concern based on our review of the Interim Final Rule. First, we question the qualifications of the QIC panel members as it relates to physical therapy claims. Second, we are concerned that contractors may be able to reopen claims to retroactively implement changes in local or national coverage decisions. Third, APTA questions the requirement that providers and suppliers submit all evidence at or before the reconsideration level, while beneficiaries are permitted to submit evidence at the ALJ level. We hope these comments and concerns are useful to CMS as the Agency moves forward with the new Medicare appeals process.

1. Conduct of a Reconsideration

Under §405.968(c) of new appeals rule, the qualified independent contractors (QICs) must have "sufficient medical, legal and other expertise, including knowledge of the Medicare program. When a redetermination is made with respect to whether an item or service is reasonable and necessary, the QIC designates a panel of physicians or other appropriate health care professionals to consider the facts and circumstances of the redetermination." APTA supports this provision of the new appeals process, but believes that in cases where physical therapy claims are reviewed by a QIC panel, physical

therapists should be the "appropriate health care professionals" reviewing the case. APTAsuggests rewording §405.968(c)(2) to include specific language designating that a QIC panel of appropriate health care professionals be in the same field as the claim under review.

Section 405.968(c)(3) provides a precedent for this reasoning, as physicians have a specific carve out: in cases where a claim pertains to the furnishing of treatment by a physician, or the provision of items or services by a physician, the reviewing professional must be a physician. However, physicians should not be the only profession entitled to peer review under the QIC reconsideration process. APTA believes that claims for physical therapy services provided by physical therapists should be reviewed by a licensed physical therapist during this part of the appeals process. Physical therapists are the most qualified professionals to conduct medical review of physical therapy claims and make appropriate Medicare coverage determinations since they have unique experience, skills and training in this field.

In the past, a number of government agencies, including the OIG and CMS, have recognized the value of having physical therapists conduct reviews of physical therapy claims. For example, the OIG issued a report in August 2001 titled "Physical, Occupational and Speech Therapy for Medicare Nursing Home Patients, Medical Necessity, Cost, and Documentation under the $1,500 Caps." The OIG conducted on-site medical and financial reviews using teams of physical therapists, occupational therapists and speech-language pathologists to review medical records and assess the medical necessity, overutilization, and quality of care provided. Because of the training and education of physical therapists, they were able to clearly identify physical therapy services that were overutilized and not medically necessary. For the same reasons, they are the best professionals to interpret documents and supporting evidence in QIC reconsiderations involving physical therapy claims, as physical therapists are specifically trained in the nuances of the profession.

CMS also has recognized the importance of having physical therapists review physical therapy claims. In Chapter 6 of the Intermediary Medical Review Guidelines in the Medicare Program Integrity Manual, CMS specified criteria for medical review of outpatient physical therapy services. Section 5.2 of this Chapter relates to the Level II review process. According to this provision, "If a bill is selected for medical review, intermediaries refer it to the Level II health professional MR staff. If possible, they have physical therapists review outpatient physical therapy bills." APTA recommends a similar provision to the "Qualifications of the QIC's panel members" section of the new appeals procedures. APTA would be pleased to work with CMS to facilitate the process of selecting qualified physical therapist reviewers for this stage of the appeals procedures.

2. Reopenings of Initial Determinations, Reconsiderations, Hearings, and Reviews

Under §405.986(b) of the appeals procedures, contractors are not precluded from reopening a case to effectuate a local or national coverage decisions issued under the authority of the Act. APTA suggests clarification of the language of this provision. Currently, the provision could be interpreted to allow contractors to reopen a case based on a local coverage decision taking effect within one year from the initial determination or redetermination. APTA is concerned

this could lead to contractors reopening decisions when coverage is no longer extended to a certain treatment. Providers could then be forced to repay contractors for payments made while the treatment was part of the local or national coverage decision. We strongly believe that CMS should not permit contractors to apply local or national coverage decisions retroactively to providers and this should be made clear in the rule. If this is not the intent of CMS, APTA recommends rewording §405.986(b) to reflect this change by specifying that coverage decisions cannot be applied retroactively under this provision, or by removing the sentence entirely.

3. Evidence Rules for Providers

Under §405.966 and §405.1028 of the rule, suppliers and providers must submit all evidence at the redetermination or reconsideration level. Absent good cause, providers and suppliers will not be able to submit new evidence at the ALJ or MAC levels. This limitation applies to providers and suppliers and not to beneficiaries – who will be permitted to submit new evidence at the ALJ and MAC levels. The limitation on the presentation of new evidence will also apply to beneficiaries represented by providers or suppliers to ensure that providers or suppliers do not circumvent this rule by offering to represent beneficiaries. While these provisions are codified under section 933(a) of the MMA, APTA disagrees with this limitation on the introduction of evidence.

CMS justifies the evidence limitation on providers and suppliers by presuming that providers and suppliers have a better understanding of the appeals process and should know what materials to submit as evidence in an appeal. APTA questions this logic, as many providers do not seem well-informed about the Medicare appeals process. As the new regulations are supposed to afford providers and suppliers with similar appeals rights to beneficiaries, limiting when providers and suppliers may introduce new evidence may put these entities at a significant disadvantage when navigating their way through the new appeals rules. To minimize confusion, APTA recommends that CMS specify the types of evidence providers and beneficiaries should present at the redetermination and reconsideration levels. Moreover, CMS should consider including additional examples in §405.1028, or issuing a separate guidance document, for providers and suppliers as to the kinds of evidence that meets (and fails to meet) the good cause standard.

Conclusion

APTA welcomes the implementation of a streamlined appeals process and one that includes increased rights for providers and suppliers. We appreciate the opportunity to comment on the Interim Final Rule, and have relatively few concerns with the new appeals procedures. In summary our three areas of issue in the Interim Final Rule are:

- Amending §405.968 to add physical therapists to physicians as professions that will have their reconsideration cases reviewed by other physical therapists during the QIC panel review.

- Clarifying §406.968(b) to ensure contractors cannot use this provision to reopen cases to retroactively implement local or national coverage determinations on providers.

- Addressing the limitation on the introduction of evidence for providers and suppliers to the redetermination and reconsideration level except with good cause, as many providers have little understanding of the appeals process.

The American Physical Therapy Association looks forward to the next steps implementation of the new Medicare appeals procedures and would be pleased to work with CMS concerning any questions or additional information APTA can provide on the appeals issue. Please contact Jonathan Morse at JonathanMorse@apta.org or at (703) 706-8547 if you have further questions.

Sincerely,

G. David Mason
Vice President, Government Affairs

Submitter :

Date: 05/07/2005

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-10-Attach-1.DOC

Comment Letter on Medicare Claims Appeal Process Changes

May 7th, 2005

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

Re: Comments on CMS-4064-IFC—Medicare Claims Appeal Procedures

Dear Sir or Madam:

Alliance Mobile Health ("the company") is a private ambulance company that provides advanced life support, basic life support, and specialty care transport services to the over 1.1 million residents of Oakland County, Michigan. We agree with the American Ambulance Association that emergency and non-emergency medical transportation is a public service, and an essential part of the public health care system.

It is in the public interest to ensure that private ambulance companies like Alliance Mobile Health receive appropriate reimbursement for services provided to Medicare and Medicaid patients. Disputes over reimbursement must be resolved in a timely fashion through an impartial process. With modification, the interim final rule has the potential to adequately ensure that the full facts pertaining to an appeal are examined, and that the resulting decision is fair, and impartial. We stand with the American Ambulance Association in requesting the reasonable and necessary changes to the interim final rule outlined below.

Reconsiderations. Section 405.966(a)(2) of the rule, implementing section 1869(b)(3) of the statute, provides that if evidence is not submitted by a provider or supplier at the qualified independent contractor ("QIC") level, it cannot be submitted during a subsequent appeal without a finding of good cause. Ambulance suppliers, through no fault of their own, are often unable to obtain a record or other documentation that may be necessary to prove their case at the reconsideration level. Lack of cooperation by a facility treating the patient or refusal of a physician to supply a letter documenting the order for an ambulance to be called are examples of such inability to produce needed evidence. The regulation needs to make clear that such occurrences, totally outside the supplier's control, would constitute good cause for such documentation to be considered at a subsequent appeal level.

ALJ Hearings. Section 405.1010(d) provides that if CMS or a contractor participates in an ALJ hearing, they cannot be called as a witness. We do not understand the purpose of this provision or how it can lead to a more complete examination of all the issues, which we understand to be CMS' objective in allowing CMS or a contractor to participate in a hearing in the first place. It is frequently necessary for a supplier to call a contractor representative, or even CMS, as a witness in order to establish the grounds on which they based their action on a claim or determination. The fact that CMS or the contractor has been made party to the hearing is irrelevant to the usefulness of such testimony. CMS or its contractors should not be able to immunize themselves against being called as a witness simply by deciding to participate as a party to the hearing. We believe you should delete this provision of the rule.

Section 405.1036(f) allows subpoenas to be requested for an ALJ hearing, but states that they must be requested within 10 days of the notice of the hearing. Furthermore, a subpoena may be requested only after discovery is sought, a motion to compel is filed and granted, and the subpoenaed party does not supply the requested records. In light of the requirement that a party

must exhaust these other efforts to obtain the records before seeking a subpoena, it is unreasonable to require that the request for a subpoena be filed within 10 days of the notice of hearing. The provision should be amended to require only that a subpoena request be filed before the decision of the ALJ. Alternatively, a party requesting a subpoena should be allowed a reasonable amount of time, after he has exhausted all other required efforts to obtain the records, to file the request for a subpoena.

Conclusion. The primary purpose of the rules should be to assure that a complete picture of the facts and circumstances is presented to the hearing officer. The government or its agent should be required to the fullest extent to ensure that the record is complete. Unfortunately, as explained above, the rules set forth in the interim final regulation too often inject adversarial procedures that may stand in the way of developing a full and accurate record upon which a decision can be based. We urge you to examine these issues with a view toward what should be our common goal—adjudicating claims on the basis of a true and accurate set of facts.

We appreciate the opportunity to submit these comments. Please let us know if we can provide any additional information or assistance.

Sincerely,

Jim Buell

Director of Operations
Alliance Mobile Health

Submitter : **Ms. Paula McCann, Esq.** **Date: 05/09/2005**

Organization : **Medicare Advocacy Project, Vermont Legal Aid, Inc.**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Issues 1-10

Medicaid State Agencies

At Sec. 405.908, the regulations appear too narrowly drawn in light of the current practices where Medicaid State Agencies have subcontracted Medicare appeals for dual eligibles to outside entities in order to fulfill coordination of benefits obligations. For example, in Vermont, the Medicare Advocacy Project (MAP) of Vermont Legal Aid represents nearly 30,000 dual eligibles as appointed representatives. In our work on behalf of our clients with Vermont Medicaid, MAP begins many of our cases with a request for a patient demand bill which differs from a routine Medicare claim submitted by a provider. The patient demand bill allows a Medicare beneficiary or their appointed representative the right to require the provider to bill Medicare and obtain an initial determination on that claim. As currently written, the interim final rule at 405.908 envisions State Medicaid Agencies as only having party status when they request a redetermination and not when a State subcontractor requests a patient demand bill under subrogation rights. We encourage CMS to reconsider and research further the ways in which State Medicaid Agencies are now fulfilling their coordination of benefits obligations under federal law through the use of subcontractors. In sum, we encourage CMS to give a broader definition to the State Medicaid Agencies as "party" at the initial stage of claims processing in addition.

Initial Determinations

At Sec. 405.920, Initial Determinations, the interim final rule at subsection (a) sets forth a notice provision that only includes sending such notice to a beneficiary and not an appointed representative. While addressing this point in the preamble at page 11442, CMS states that while it understands appointed representatives need notice of initial determinations, it is felt that appointed representatives should not be mailed MSNs due to potential extraneous information that may, or may not, appear on the MSN. For example, other claims information may be on the MSN that is unrelated to the appeal. As the Medicare Advocacy Project at Vermont Legal Aid, our appointment of representative form allows us to view certain claims processing information related to our clients for a set period of time regarding their Medicare benefits. As lawyers, even if we were exposed to irrelevant claims information in the pursuit of our appeals, we are bound to protect such information as confidential under the Rules of Professional Conduct. If CMS does not feel that it can release MSNs to appointed representatives, then CMS and its contractors certainly have sufficient intellectual and mechanical resources to find an alternate method of notice that can be sent to appointed representatives to keep us informed of initial determinations. In light of the new time frames for filing for reconsideration, effective and immediate notice of initial determinations to appointed representatives should be an integral part of any CMS redesign of Medicare appeals in order to assure that Medicare beneficiaries can be effectively represented in this new process.

Reopenings of Initial Determinations, Reconsiderations, Hearings, and Reviews

At Sec. 405.986, the language proposed is far more restrictive than the current regulations relied upon at 20 CFR Sec. 404.988(b), Conditions for reopening, and at 404.989, Good cause for reopening. For nearly 40 years, the accepted practice in Medicare appeals has followed a less restrictive standard for reopening an initial determination, reconsideration or ALJ decision. Under the interim final rule, new and material evidence can only be used to reopen a case if it was not available or known at the time of the determination or decision. This phrase is left wholly unexplained and will lead to significant confusion in the appeals process. We have already seen some Medicare contractors attempting to apply this new rule with poor results for all concerned. For example, a recent case in our project involved a beneficiary filing for reopening for a denied wheelchair claim which was several years old. The beneficiary was not involved in their DME provider's appeal in this matter and they were simply told Medicare would not pay for their chair. Several years later, the beneficiary found out that Medicare should have paid for the chair and sought to reopen the original denied initial claim. The initial claim was denied due to an error on the CMN submitted by the provider (lack of identifying wheelchair serial number, make and model). This error was easily remedied by the beneficiary's appointed representative and a reopening was requested. The Medicare contractor denied the reopening, claiming that the revised CMN was not "new and material" since it was information available at the time of the initial determination. The information was available to the provider, but it was not available to the beneficiary. The beneficiary should not be penalized under this new definition of reopening and good cause for materials that may have existed but were not within their sphere of control or understanding at the time of the initial determination. Forty years of well-known and functional standards for reopening and good cause should not be abandoned so easily by CMS, especially in light of the confusion and fundamental unfairness that will result to beneficiaries in pursuit of valid claims for coverage from Medicare by application of this newer and far more restrictive standard.

Issues 11-17

ALJ Hearings

At Sec. 405.1010 and 405.1012, CMS has defined for itself and its contractors several opportunities to be heard as a party at ALJ level of appeal. First, CMS or its contractors can be invited by the ALJ to "participate" by filing position papers but cannot be called as witnesses or cross-examined. CMS or its contractors can elect to be a party and, as such, they can call witnesses and cross-examine witnesses, but cannot be called to testify or be cross-examined themselves. These new mechanisms for CMS to insert itself into an ALJ hearing as essentially opposing counsel turns the agency into an adversary of the Medicare beneficiary. The first three levels of appeals (initial claim processing, reconsideration and QIC) are all controlled by Medicare contractors who apply Medicare policy, even when it is in direct conflict with regulation and law. The ALJ hearing process is suppose to be a neutral appellate forum where the lower level record is reviewed by an impartial judge and where the beneficiary can speak, usually for the first time, either directly or through appointed representatives, about why they believe they qualify for Medicare covered services under the law. Medicare law is complex and the choice CMS is forcing beneficiaries to make in these two provisions is unsupportable. Either a beneficiary has to go to hearing before a federal ALJ by themselves with no support, and try to understand the law and advocate for themselves in spite of illness, advanced age, or disability; or their appointed representative will enter the fray for them against a battery of Medicare financed contractors or policy makers whose sole purpose at hearing is to stop the beneficiary from obtaining coverage. It seems that what has been lost here is the understanding that this current generation of Medicare beneficiaries took a leap of faith with our government back in 1966. In that year, working Americans began paying a tax to fund Medicare Part A when no one could really tell them what the benefits would be for them when they reached 65 or became disabled. Today, Medicare beneficiaries pay Part B premiums of nearly $80 a month currently, they pay copayments and deductibles, and they are about to have to pay for Part D premiums for a limited drug benefit. It is unconscionable that Medicare dollars, which are used to pay contractors and CMS staff, will be used to fund adversaries at ALJ hearings to argue against beneficiaries trying to obtain Medicare covered benefits.

Submitter : Mr. Irwin Cohen **Date:** 05/09/2005

Organization : Fulbright & Jaworski LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Mr. Andrew Koski **Date:** 05/09/2005

Organization : Home Care Association of NYS

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4064-IFC-13-Attach-1.DOC

Cmt#13

HOME CARE ASSOCIATION
of New York State, Inc.

May 9, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

Dear Sir/Madam:

The following are comments of the Home Care Association of New York State on CMS-4064-IFC, Changes to the Medicare Claims Appeal Procedures. The Home Care Association (HCA) of New York State represents over 200 agencies providing Medicare, Medicaid, and private pay home care services to over 400,000 older and young disabled individuals in New York State, including 180,000 Medicare beneficiaries and 210,000 Medicaid recipients. HCA provides comments on federal and state regulations and legislation that affect home care providers and consumers.

I. In-Person ALJ Hearings Should Not Require A Demonstration of Good Cause and Should be Held in New York

The interim rule requires Administrative Law Judge (ALJ) hearings to be conducted by videoteleconferencing (VTC) if the VTC technology is available, by phone if the record suggests that a telephone hearing may be more convenient or in-person if VTC technology is not available or "special or extraordinary circumstances exist" [section 405.1020 (b)]. Furthermore, the ALJ may grant a request for an in-person hearing upon a finding of "good cause" [section 405.1020 (i) (5)]. These requirements virtually eliminate the right to an in-person hearing and should be changed so that in-person hearings can be held without a finding of special or extraordinary circumstances or "good cause." Some providers and beneficiaries have found in-person hearings to be a more appropriate venue for their appeals and they should not have to justify the continued use of this option.

The Department of Health and Human Services has indicated that it intends to assign 15 ALJs to appeal offices in Cleveland, Ohio; Miami, Florida; and Irvine, California and five additional ALJs to a headquarters office in Arlington, Virginia. For those providers and beneficiaries who want to utilize in-person hearings, CMS needs to establish appeal office locations in New York City and an upstate New York location. The previously mentioned sites are not accessible to New York State providers or residents and will result in elimination of the opportunity for an in-person hearing.

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II. The Requirement that ALJ decisions be Issued within 90 days Should Not be Waived for In-Person Hearings

The interim rule waives the requirement that ALJ decisions be made within 90 days of the hearing request when an in-person hearing is held [section 405.102099(h)(4)]. This time frame should not be waived for in-person hearings because it will only lead to delays in implementation of favorable decisions and delays in further appeals of unfavorable determinations. Eliminating the 90-day time frame is another way to discourage providers and beneficiaries from exercising their right to an in-person hearing.

III. ALJs and the MAC Should Not Give Deference to LCDs or LMRPs

The interim rule requires ALJs and the Medicare Appeals Council (MAC) to give "substantial deference" to local coverage determinations (LCDs), local medical review policies (LMRPs), or CMS program guidance, such as program memoranda and manual instructions, if they are applicable to a particular case [section 405.1062(a)]. This is a substantial change from the current practice of ALJs being bound by regulations and not either LCDs or LMRPs. HCA is opposed to ALJs and MACs giving deference to LCDs and LMRPs because this will have a detrimental impact on home care providers and their clients who often have to appeal incorrect intermediary determinations based on these policies related to complex issues such as "homebound," "restoration potential," and "medical necessity."

IV. The Role of CMS and Its Contractors Should be More Limited at ALJ Hearings

The interim rule allows CMS or one its contractors to elect to "participate" in an ALJ hearing by filing position papers or providing testimony [section 405.1010 (a)(c)] and to be a "party" to an ALJ hearing by filing position papers, offering testimony, submitting new evidence and calling witnesses or cross-examining the witnesses of other parties [section 405.1012(c)]. These provisions change the nature of an ALJ hearing from a provider or beneficiary-friendly process to a more legal and adversarial process. By allowing CMS or its contractors to appear and present information and/or testimony at ALJ hearings, the balance of authority shifts and providers and beneficiaries will have a much more difficult burden of proof to overcome. CMS and its contractors should not be allowed to appear and advocate their position at ALJ hearings unless requested by the ALJ.

V. Time Frames Need to be Established for Contractors to Issue Determinations on Requests for Reopenings

While the interim rule establishes time frames for providers to request reopening of cases [section 405.980(c)], there is no time frame for contractors to make determinations on such requests. Time frames need to be established for contractors because providers have only 120 days to request a redetermination and they may miss that deadline awaiting a contractor's determination on their request for reopening.

VI. Decisions on Whether to Grant a Request for Reopening Cannot be Appealed

The interim rule states that the contractor's, Qualified Independent Contractor's (QICs), ALJ's or MAC's decision on whether to reopen a case is final and not subject to appeal [405.980(a)(5)]. This needs to be changed so that such decisions can be appealed. Not allowing appeals places too much authority in the hands of those parties.

VII. Providers Should be Allowed to Submit Additional Evidence After the QIC Level

The interim rule requires providers and beneficiaries represented by providers who are filing a request for QIC reconsideration to submit all evidence and does not allow for subsequent consideration of new evidence absent a demonstration of "good cause" [section 405.966(a)(2)], but does not define good cause. Furthermore, an ALJ can allow for the submission of new evidence but only if good cause exists; for example, the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration (sections 405.1018(c) and 405.1028(b)]. This is too high of a standard to meet and should be changed to allow providers to submit new evidence that was not available at the time of the request for either a QIC reconsideration or an ALJ hearing. Lastly, if CMS is allowed to be a party to an ALJ hearing and submit new evidence, providers should be afforded the same right whether or not CMS is a party.

Thank you for the opportunity to provide comments on CMS-4064-IFC. If you have any questions or need further information, please call me at 518-426-8764, ext. 224.

Sincerely,

Andrew Koski
Vice President for Advocacy and Public Policy

Submitter : Mr. Irwin Cohen **Date:** 05/09/2005

Organization : Fulbright & Jaworski LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-14-Attach-1.DOC

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May 9, 2005

BY ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on Interim Final Rule regarding Changes to the Medicare Claims Appeal Procedures, CMS-4064-IFC

Dear Madam or Sir:

We are submitting the following comments regarding the changes to the Medicare appeals procedures announced in the interim final rule published in the March 8, 2005 Federal Register on behalf of our client, the Diabetic Product Suppliers Coalition ("Coalition"). The Coalition is a national organization representing the interests of direct-to-customer suppliers of diabetic care products. The majority of the members of the Coalition have been parties to Medicare Part B appeals, and are quite familiar with the problems that plague the current appeals process, and just as importantly, the problems that we anticipate will ensue if many of the provisions detailed in the interim final rule are allowed to stand.

We wholeheartedly support the need to reform the current Medicare appeals system, and were proponents of the changes made by Congress in the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Public Law 106-554. We believe, however, that many of the provisions in this interim final rule will create more fundamental problems with the Medicare appeals system than currently exist, in contradiction of the clear intent of Congress in its passage of the BIPA provisions. While some of the rule's provisions will help ensure a fairer and more expeditious Medicare appeals system, many other provisions will lead to inequitable results that will ultimately undermine the system.

In addition to our concerns regarding the appeals process generally, we are equally concerned about who will hear Medicare appeals. As addressed in the preamble of the interim final regulation (70 Fed. Reg. 11420, 11422), section 931 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), requires that the functions of ALJs responsible for hearing Medicare appeals be transferred from the Commissioner of the Social Security Administration to the Secretary of Health and Human Services (the "Secretary" or

"HHS"). The ALJs are required "to be organizationally and functionally independent from Centers for Medicare and Medicaid Services ("CMS") and must report to and fall under the general supervision of [the Secretary]." *See* 70 Fed. Reg. at 11422. We believe that the issuance of the regulations by CMS itself, and the content of the provisions is a strong indicator of CMS's attempt to not only influence, but to control the decision-making process in clear defiance of Congressional intent. CMS should simply not be the party promulgating these regulations. Instead, these regulations should have been promulgated using negotiated rulemaking, with the health care community and the Secretary's office.

These regulations place restrictions on appeal rights which have the serious potential to erode the independence and impartiality of ALJs, which could make a mockery of the Medicare appeals system. Any legitimate appeals system should provide parties a fair opportunity to be heard and result in decisions from arbiters (such as ALJs) that are solely based on the merits of the case presented.

The Coalition is concerned that the appeals system outlined by the Secretary (*i.e.*, the ability of CMS to be a party, the submission of evidence requirements, etc.) is stacked overwhelmingly in favor of CMS and its contractors, and, as a consequence, beneficiaries and suppliers will not have the legitimate opportunity to present their case before an impartial tribunal Put simply, beneficiaries and suppliers *will be unable* to get fair and impartial hearings and, just as importantly, will find it difficult to receive unbiased decisions based solely on the merits of the case at issue.

I. Video and Telephone ALJ Hearings

Related to the transfer of ALJ functions are the provisions that encourage video teleconferencing ("VTC") and telephone hearings at the expense of in-person hearings. *See* 42 C.F.R. § 405.1020. In the preamble (70 Fed. Reg. at 11456-57), the Secretary discusses in great detail why it favors the use of VTC and telephone hearings, including the convenience, the greater facility in obtaining expert witnesses, and the decrease in the travel time of ALJs. The Secretary so favors the use of VTC and telephone hearings that *in-person hearings can only be granted if an appellant shows good cause as to why such a hearing is warranted.* 42 C.F.R. § 405.1020(e). More importantly, a request for an in-person hearing constitutes a waiver of the 90-day time frame within which an ALJ must render a decision – a deadline established by statute. 42 C .F.R. § 405.1020(i).

While such a provision may appear innocuous at first blush, a closer reading raises a number of important issues, the most notable of which are: i) whether there are enough VTC facilities around the country to handle the incredible number of cases that will be handled by video technology; ii) the procedural consequences of not having enough facilities to have cases heard and what those delays will do to the statutorily mandated time frames within which an ALJ decision must be rendered; and iii) the legality of cavalierly ignoring timeframes mandated by statute when an appellant show good cause for an in-person ALJ hearing. For many beneficiaries and suppliers, in-person hearings are the best avenue by which to present their arguments and their evidence. In-person hearings should not be a default alternative for which the appellant must show good cause, and then be punished by having the 90-day time frame for ALJ decisions waived. At the very least,

the Secretary should provide that in the event of an in-person hearing, an ALJ will *have 90 days from the date of the hearing* (as opposed to 90 days from when the hearing request is received) within which to render a decision, thereby still upholding the timely due process rights of appellants who decide to avail themselves of in-person hearings.

Ultimately, the Coalition believes that while VTC may be encouraged, an appellant who wishes to have an in-person hearing should not have to show "good cause" for requesting such a hearing.

II. Parties to a Hearing

Under the regulation, CMS or its contractors, including a QIC, may be party to an ALJ hearing, and, as such, may file position papers or briefs, call and cross-examine witnesses, and provide testimony. *See* 42 C.F.R. § 405.1012. The decision as to whether to join an appeal as a party is left to the sole discretion of CMS – the ALJ may not require CMS to be a party. The regulation only requires that CMS notify the ALJ within 10 days after receiving the notice of hearing that it intends to participate in the hearing as a party. Such a provision will ultimately turn ALJ hearings in which CMS is a party into adverserial proceedings, contrary to the original intent of the Medicare program. Such a change was never envisioned by Congress, nor the Administrative Procedures Act. We oppose permitting such participation by CMS or its contractors.

If the Secretary insists that CMS or its contractors will be permitted to participate as a party in the appeals, we then believe federal law obligates a federal agency to award attorney and other fees to prevailing appellants in what would be adversary proceedings. Under the Equal Access to Justice Act as codified in 5 U.S.C. § 504 (2004) ("EAJA" or the "Act"), an agency:

> [That conducts an *adversary adjudication* shall award, to a prevailing party other than the United States, fees *and other expenses incurred by that party in connection with that proceeding*, unless the adjudicative officer of the agency finds that the position of the agency was substantially justified or that special circumstances make an award unjust.

5 U.S.C. § 504(a)(1). An "adversary adjudication" is defined as an adjudication under 5 U.S.C. § 554 in which the position of the government *is represented by counsel.* 5 U.S.C. § 504(b)(1)(C). The Act defines a "party" as an individual whose net worth does not exceed $2,000,000 at the time the adversary adjudication was initiated, or any owner "of an unincorporated business, or any partnership, corporation, association . . . the net worth of which did not exceed $7,000,000 at the time the adversary adjudication was initiated, and which had not more than 500 employees." *Id.* § 504(b)(1)(B). The term "fees and other expenses" includes: 1) the reasonable expenses of expert witnesses; 2) costs of tests, studies, and reports necessary for the preparation of the party's case; and 3) reasonable attorney's fees. *Id.* § 504(b)(1)(A).

The Secretary, however, has noted that no award of attorney fees may be made against the Medicare Trust Fund. The mere fact that fees may not be awarded from the Trust Fund does not obviate the Secretary's obligation under federal law to pay fees to prevailing appellants in adversary adjudications. Fees may be awarded from other sources including CMS and carrier operating funds. The Secretary cannot have it both ways. On the one hand, the Secretary would like CMS to be a party to ALJ hearings at its discretion thereby turning Medicare appeals into adversary proceedings. However, contrary to clearly stated federal law, the Secretary refuses to allow the award of attorney and other fees for appellants when they prevail in what are clearly adversary proceedings. Such an approach is manifestly unfair, and, more importantly appears to be a *per* se violation of federal law. We urge, therefore, that if the Secretary is unwilling to award fees to appellants, he should rescind his proposal to permit CMS or its contractors to join ALJ hearings as parties, and keep the current ALJ hearing policies in place.

A. CMS Participating in Hearing

While we have no objection to CMS or its contractors participating in ALJ hearings, we strenuously object to the provision which does not permit the agency or its contractor to be called as witnesses during the hearing. 42 C.F.R. § 405.1010(a) – (e). If CMS or its contractor can file position papers, provide testimony, and clarify factual or policy issues (42 C.F.R. § 405.1010(c)), principles of due process certainly would require that CMS or its contractor be able to be called as witnesses. The agency cannot be allowed to present all the information it wants without also being obligated to appear as a witness should the ALJ or appellant so decide, especially when appearing as a witness is directly related to whatever submissions or testimony the agency or its contractor made in the case. The rule should be simple: should CMS choose to participate in a particular ALJ hearing, it is then subject to appearing as a witness in that hearing if the subject of the testimony involves the papers, information, and/or testimony submitted or provided by the agency.

III. Submission of Evidence

A. ALJ

The interim final rule requires parties to submit all written evidence they wish to have the ALJ consider with the request for hearing, or within 10 days of receiving the notice of hearing. The evidence must be accompanied by a statement explaining why it was not submitted at the previous reconsideration level. 42 C.F.R. § 405.1018. Prior to the hearing the ALJ then will consider whether the appellant had good cause for first providing the evidence at the ALJ level. If the ALJ determines there was not good cause, the ALJ must exclude the evidence from the proceeding and cannot consider such evidence in reaching a decision. 42 C.F.R. § 405.1028(c).

Nothing in the language of the statute rejects the current ALJ policy of treating ALJ hearings as *de novo* proceedings. While we understand that the language of the MMA (section 933) requires the full and early presentation of evidence, we believe that the Secretary's provision unfairly hampers the ability of appellants to submit evidence, or, at the very least, makes it cumbersome to submit new evidence because what constitutes "good cause" is not made very clear, and does not seem to reflect the realities of the appeals process. Many documents necessary for an appellant to

conduct a hearing, such as statistical sampling documents, do not come into possession of the appellant until prior to the ALJ hearing principally because the documents are not made available by either the carrier or intermediary until that time. Appellants should not be penalized (*i.e.*, drafting of a statement showing good cause) for circumstances beyond their control. The current *de novo* posture of ALJ hearings has, in fact, permitted fairer and better decisions to be able to be reached, than would be possible if evidence was limited to what was submitted at the earliest level of appeal. Limiting evidence goes against the fabric of justice and rights accorded any appellant. Proposals of this nature suggest an attempt by the government to inappropriately limit the rights of appellants to fair and impartial adjudication.

Accordingly, we believe the Secretary should keep in place the current rules regarding evidence submission at ALJ hearings.

B. Medicare Appeals Council

Under the rule, review by the Medicare Appeals Council ("MAC") is supposedly *de novo*. However, in a provision that clearly undermines the *de novo* posture the Secretary announces, the rule limits the MAC's review to "the evidence contained in the record of the proceedings before the ALJ." If the hearing finds a new issue that the parties were not afforded the opportunity to address at the ALJ level, the MAC will consider any evidence related to that issue that is submitted with the request for review. If the MAC determines that additional evidence is needed to resolve the issues in the case and the record indicates that the parties or previous decision makers did not attempt to obtain the evidence, the MAC may (but is not required to) remand the case to the ALJ to obtain the evidence and issue a new decision.

Given these restrictions, it does not appear that the MAC review is, in fact, a *de novo* review. If the Secretary intends to make MAC reviews *de novo*, he should remove all the restrictions he intends to implement, and allow MAC to review the case as it sees fit, and hear any evidence it decides is pertinent. After all, that is the intent and design of *de novo* reviews – allow a tribunal to hear the merits of a case without being bound by what occurred at an earlier level of review.

IV. Reopening

The final rule provides that a contractor may reopen or revise its initial determination or redetermination on its own motion "[a]t any time if there exists reliable evidence . . . that the initial determination was procured by fraud or similar fault . . . ." 42 C.F.R. § 405.980(b). The term "similar fault is defined as follows:

> [T]o obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim . . . .

42 C.F.R. § 405.902.

We take exception to the definition of "similar fault." The definition would effectively permit unlimited reopening for a wide variety of disallowances, and is so broad as to include virtually any claim with which the contractor takes exception. It will emasculate the limitations on reopening. We believe that "similar fault" should be defined as "a violation that would have been subject to a finding of fraud, had the requisite intent been evident." Thus, failures to comply fully with contractor guidelines, provider bulletins, practices in the community, or previous disallowances, would not be viewed as "similar fault" to fraud.

The question of what is "similar fault" has been an issue in several ALJ cases about which we are aware, all of which held that the term is to be defined as we have recommended above. None of these cases, to our knowledge, were overturned by the MAC.

V. ALJ Deference to Policies Not Issued Under the APA

The rules require that the QIC, an ALJ, or the MAC give deference to CMS policies, such as local medical review policies("LMRP"), CMS program memoranda, and CMS policy manuals, that are not issued pursuant to the Administrative Procedures Act. The rules place the burden on the party to prove why the reviewer should not give deference to the policy, and an ALJ or the MAC that decides not to follow a policy must include in its decision the reason for not applying the policy. This is in direct contravention to the intent of the BIPA provision which specifies that QICs, like ALJs, are only bound by the law, regulations, CMS rulings, and national coverage determinations. This regulation would limit the abilities of the QIC to review LMRPs on an even playing field and result in much the same level of appeals to the ALJs, a scenario that the BIPA provisions were trying to avoid.

It would also result in many cases not being resolved at the ALJ or MAC level, putting a heavy burden on the courts and further extending the appeals system in direct contravention to the intent of the BIPA rules. This is simply an unjustified limitation placed on the appeals adjudicators.

Thank you for the opportunity to comment on these regulations.

Very truly yours,

Original signed by Irwin Cohen

Irwin Cohen

cc (by e-mail): Diabetic Product Suppliers Coalition Members

Submitter : Mr. Hal Daub **Date:** 05/09/2005

Organization : American Health Care Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-4064-IFC-15-Attach-1.DOC

Cmt#15

202-898-2828
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May 9, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Attn: CMS-4064-IFC

***Re: Comments On Medicare Program: Changes to the Medicare Claims Appeal Procedures, Interim Final Rule with Comment Period,* 70 Federal Register 11420, (March 8, 2005), CMS-4064-IFC**

Dear Dr. McClellan:

The American Health Care Association ("AHCA") appreciates the opportunity to comment on the above-referenced interim final rule, *Medicare Program: Changes to the Medicare Claims Appeal Procedures* (the "Interim Final Rule"). AHCA is a federation of affiliated long-term care provider associations representing some 10,000 nonprofit and for-profit nursing facilities, skilled nursing facilities ("SNFs"), assisted living and residential care facilities, sub-acute providers, and intermediate care facilities for the mentally retarded and developmentally disabled. AHCA and its membership are committed to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in SNFs, assisted living residences, and other facilities. The vast majority of our member long-term care facilities participate as SNFs in the Medicare program. Therefore, AHCA and its members have a direct interest in the changes to the Medicare appeal process for claims under both Medicare Part A and Part B.

I. Introduction

AHCA has a long-standing interest in addressing the short-comings in the Medicare appeals procedures and advocating for meaningful change. For example, AHCA participated as an *amicus curiae* in *Shalala v. Illinois Council on Long Term Care,*

Inc., 529 U. S. 1, (2000), to illustrate the severe limitations on the ability of a provider to challenge the legality of Medicare regulations or policy. Under the Supreme Court's decision, virtually all claims must be brought through the Centers for Medicare & Medicaid Services ("CMS") administrative review process. This was true even where the administrative process existing at the time:

- did not permit rulings on statutory or constitutional issues;
- where certain determinations could not be appealed to the administrative process;
- where some providers would have to accept draconian sanctions – including termination from participation in the Medicare program altogether – before gaining access to the administrative review process; and
- where delayed review through the multi-layered administrative process could mean no meaningful review at all.

AHCA was and remains deeply concerned that the 5-4 decision, illustrating the split within the Court on this controversial issue, essentially foreclosed timely judicial review of Medicare regulations or policy. It also conflicts with the overwhelming presumption of judicial review of agency action.

As a result, AHCA was a strong advocate of legislative solutions to address some of the limitations imposed by *Illinois Council*. This included advancing legislation to 1) allow for direct judicial review of Medicare regulations and policies under federal law where there are no facts in dispute and the party seeks a declaratory ruling on the legality of a regulation or policy, and (2) impose reasonable deadlines for administrative review, and that failure to meet such deadlines enables the party requesting review to proceed to the next level of review, and ultimately judicial review, on a timely basis.

Beyond the problems with the costly and protracted administrative appeals process, the different rules for appeals under Medicare Part A and Part B have caused considerable confusion for AHCA's member facilities and the beneficiaries they serve. Accordingly, AHCA was instrumental in supporting legislation that eventually became part of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA") and the related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").

AHCA commends CMS for its efforts in the Interim Final Rule to establish uniform appeal procedures for both Part A and Part B claims; to reduce the decision-making time for most appeals, including the right to escalate a case that is not decided on time; to use Qualified Independent Contractors ("QIC") and QIC review panels to

enhance the role of medical professionals in cases involving medical necessity; and to provide for a more efficient appeals process for providers, beneficiaries and contractors. We agree with CMS that over time, the new procedures should lead to more timely appeals decisions, significant reductions in the need to pursue appeals at the later stages of the appeals system, and a workable mechanism for appeals of matters that cannot be addressed at earlier stages of appeal to be considered by the appropriate reviewing entity. AHCA appreciates the challenge in this major overhaul of the Medicare appeals process and the need for transition and education of all interested parties. In this regard, CMS should continue its efforts to educate and solicit input from interested parties through "Open Door" sessions, issuance of sub-regulatory guidance, and other appropriate venues.

Regarding implementation of the new appeal requirements, we do not agree with CMS's decision to implement the changes initially for Part A claims determinations of Fiscal Intermediaries ("FIs") (p. 11425). There should be an equal number of QICs ready to conduct Part B reconsiderations in May 2005 as well. This appears to be the result of poor planning by CMS. However, we do not believe this will have a material adverse affect on appellants.

II. Comments on Appeal Rights

A. "Basis and Scope," Definitions, etc.

In the Interim Final Rule, CMS adopts uniform terminology for sequential steps of the claims appeal process. CMS also elaborates on how beneficiaries can appeal, appointment of representative, and prohibition on collecting a fee if the provider or supplier, who is a party to the claim, is appointed as a representative by a beneficiary. This follows current practice that when a provider or supplier accepts assignment and represents the beneficiary in the appeal, the provider or supplier may not collect any more than the applicable coinsurance or deductible from the beneficiary if the amount is valid.

AHCA supports CMS's proposal to permit providers and suppliers equal rights to beneficiaries in the appeal. We also welcome the provision permitting appeals by an involved party when a beneficiary dies. We request additional clarification on the difference between beneficiary appointment of representative and the assignment of appeal rights, as the preamble discussion is confusing and somewhat contradictory. Also, AHCA requests greater clarification of when appointment or assignment is necessary and allowable, especially given the fact that the Interim Final Rule grants providers and suppliers equal appeal rights. While we recognize the discussion and provisions in 405.944(c) and 405.964(c) that if more than one party timely files a request for a redetermination on the same claim the contractor or QIC must consolidate the separate requests, we think the process would be enhanced by requiring the contractor to provide notice to all affected parties. In that way, a provider will know if a beneficiary has already appealed a claim denial. AHCA also recommends that the contractor be required to assign a contact or reference number

to all appeals. Currently, the use of the HIC number can be confusing when there are multiple dates of service and misleading for certain provider appeals.

B. Appointed Representatives

The Interim Final Rule clarifies who can serve as an appointed representative and the process for appointment. The Interim Final rule also elaborates on the circumstances for fee collection. Specifically, a provider or supplier who is party to the claim and is appointed the representative cannot collect a fee to represent the beneficiary. Also, if a claim involves waiver of liability and the provider or supplier is representing the beneficiary, the provider or supplier must agree to waive fee. These are, for the most part, a continuation of current policy.

AHCA supports clarification of the rules regarding appointment of representatives, but as noted above, also seeks clarification on how these rules relate to an assignment of an appeal. For example, we assume CMS intends that a beneficiary can appoint a lawyer or non-lawyer to represent the beneficiary at the appeal or the provider if the provider had not appealed the claim directly.

C. Assignment of Appeal Rights

The Interim Final Rule provides that if a provider or supplier that furnished the item or service at issue accepts a beneficiary's assignment of appeal rights, the provider or supplier must waive the right to any payment from the beneficiary for handling the appeal. This does not prohibit recovery where the provider or supplier has furnished and the beneficiary has signed an Advance Beneficiary Notice ("ABN") accepting responsibility for payment. CMS states it is developing a standardized form for assignment of appeal forms, and AHCA welcomes such a form to assist beneficiaries in this process.

Given the fact that the Interim Final Rule grants providers and suppliers equal appeal rights to beneficiaries, AHCA requests clarification of when assignment of appeal rights is necessary or appropriate. We assume this would be where a beneficiary wants to appeal and wishes for the provider or supplier to handle the appeal, but the provider or supplier has not already filed an appeal.

D. Initial Determinations

The Interim Final Rule retains existing provisions of what CMS views as an initial determination for purposes of appeal. CMS has added six items that do not constitute initial determinations. With very little discussion, CMS has added a provision, based upon the amendments made in the MMA, that determinations by the Secretary of "sustained or high levels of payment errors" and prior determinations related to coverage of physicians' services are not appealable.

AHCA has a number of concerns regarding the new provision precluding appeal for determinations by the Secretary of sustained or high levels of payment errors in 405.926(p). First, AHCA requests that CMS add a definition of "sustained or high levels of payments errors." Such an open-ended phrase could be construed far too broadly, thereby denying providers their legitimate appeal rights. Second, CMS should specify how such determinations will be made. Will contractors make this determination based upon CMS guidance on CERT or DAVE reports? Does this provision apply to high denial rates calculated from random or probe reviews? Does this provision apply to providers under Focused Medical Review ("FMR") or Progressive Corrective Action ("PAC")? Third, AHCA strongly recommends that CMS be required to review dismissals on the grounds that the claim involves a "sustained or high error rate" for appropriateness and statutory compliance regarding determinations for claim errors and denials. Fourth, AHCA requests clarification of the implications of such a ruling. Finally, CMS should provide a mechanism for providers to be removed from this sanction, and to exclude certain other claims from the appeals prohibition. AHCA suggests that a party subject to appeals denial on this basis be permitted to petition CMS for removal, explaining the circumstances that may have led to the high payment errors and the corrective actions that the party has taken to address the perceived problems.

In addition, in 405.926(s), CMS says that claims submissions on forms, or formats that are incomplete, invalid or do not meet the requirements for Medicare claims and are returned or rejected to the provider or supplier are not appealable. If this provision only applies to so-called "Return-to-the-Provider" ("RTP") claims processing actions, it is acceptable since the provider or supplier can correct the error and resubmit the claim. However, AHCA seeks confirmation that this provision would not preclude review where a claim is put into "suspend" for medical review when information is missing from medical necessity or coverage perspective.

E. Redeterminations

CMS' Interim Final Rule requires requests for redeterminations to be filed within 120 days for Part A and Part B. For purposes of filing a timely request for a redetermination, the date of the initial determination will be presumed to be 5 days after the date of the notice unless there is evidence to the contrary. There is a process for extending the time frame for filing based upon "good cause." CMS has also adopted a uniform location for filing the redetermination request – the request is always filed with the contractor.

As noted, AHCA supports the uniform appeals process for Part A and B. We are hopeful that this will promote a faster resolution of Part B claims. We also support the elimination of alternative filing locations. It will be easier and clearer to have one filing location. AHCA also endorses the concept of making standardized appeal forms readily available, to include using the Medicare Summary Notices ("MSN") as the basis for requesting redetermination.

F. Reconsiderations

BIPA created a third level of review, the reconsideration, which replaces the Part B Fair Hearing and adds another review step for Part A claims before the ALJ level of review. The reconsideration is handled by the QICs. Parties to the redetermination have 180 days to request reconsideration by filing a request at the location indicated on the redetermination notice. Again, reconsiderations filed by beneficiaries and the provider or supplier will be consolidated, and the time for issuing a decision runs from receipt of the last-filed appeal.

Because of the complexity and cost of implementing a new level of review, CMS has decided to phase in the reconsideration process. Starting May 1, 2005, appeals of redeterminations by the FIs, including hospital, skilled nursing facility, home health, outpatient hospital services, and hospice claims, will go through the QIC reconsideration. Appeals of Part B redeterminations involving claims for doctor's services, durable medical equipment and other Part B items and services will continue to go to a fair hearing for the rest of 2005. Reconsiderations of Part B determinations issued on or after January 2006 will be conducted by the QICs. As noted, we are disappointed the QICs are not available for Part B claims until January 2006, but urge CMS to ensure such implementation takes place on a timely basis.

In order to achieve the statutory deadlines for review, CMS makes clear that the reconsideration level of review is a paper review. However, CMS states that QICs may contact beneficiaries, providers and suppliers with questions or for input on the case. We recommend that CMS encourage QICs to make use of this option where necessary to obtain all relevant evidence in the case.

Under the Interim Final Rule, providers and suppliers are required to submit all of the evidence they want considered in the claim to the QIC. Evidence not submitted may be excluded at subsequent levels of review. The Interim Final Rule establishes an exception to allow beneficiaries and state Medicaid agencies to submit documentation that was specified as missing in the notice of redetermination at any time during a pending appeal. This provision does not apply to beneficiaries who are represented by providers or suppliers. Each time a party submits additional information, the QIC's 60-day decision making timeframe is automatically extended by up to 14 calendar days for each submission. Without any discussion or explanation, CMS takes the position that the "fully and early presentation of evidence requirement" does not apply to itself. Therefore, this provision does not limit CMS ability to introduce evidence at the ALJ (or Medicare Appeals Council ("MAC")) level.

AHCA supports the use of QICs to resolve matters earlier in the appeal process. AHCA requests that CMS, with input from affected parties, establish a mechanism to ensure that these entities are truly *qualified* to address Medicare claim denials and clearly *independent.* AHCA's members' experience has been that in the past a truly unbiased review did not occur until the ALJ level when the presiding adjudicator had

no affiliation with the FI or carrier. AHCA is hopeful that the QICs can provide such a reasoned and unbiased review at a lower level, thus generally avoiding the need to continue up to the ALJ level of review or beyond. This would reduce time and expenses of all parties involved in the appeals process.

AHCA recognizes the value of submitting evidence early in the appeals process. We note, however, that this could raise due process concerns for appellants in cases where the FI or carrier does not provide all of the relevant information or documents to the appellant prior to this level of review (*e.g.*, in complex cases involving multiple claims, statistical sampling, or other calculations underlying the contractor's decision to deny the claims). AHCA suggests that CMS establish an exception for information that is not customarily provided to the appellant at earlier stages of the determination and appeals process, or that the appellant does not ordinarily possess. Such information, which may need to be requested from the contractor during the appeals process, should be admissible at any stage of the appeals process. This includes responding to CMS submissions, which, as noted, are admissible at any level of appeal.

G. Conduct of a Reconsideration

Under the Interim Final Rule, CMS provides that a QIC is to give substantial deference to a national coverage determination ("NCD"), local coverage decision ("LCD") and local medical review policy ("LMRP"), and may decline to follow a NCD, LCD, LMRP policy in a particular case either at the request of a party or at its own discretion. If a QIC fails to meet the deadline for issuing a decision, appellants can seek escalation of the claim to the next level.

AHCA welcomes clarification on the resources used and applied and each level of appeal. We also applaud CMS' decision to give QICs more leeway to evaluate the applicability of a NCD, LCD, LMRP or other CMS guidance in a particular claims denial. We also suggest CMS specifically allow consideration of professional standards of care and best practices as published in professional literature as applicable in a particular case. AHCA also supports providing consequences for failing to issue timely decisions as a way to promote a faster and more efficient appeal system.

With respect to the standard rule that reconsiderations will be heard by the QIC for the state in which the services were rendered, AHCA requests an exception for chain providers. In appeals of claims involving providers that have elected a single FI, AHCA suggests that providers have the option of having the claims heard by the QIC for the state in which the provider's home office is located or the state in which the services were rendered.

H. Reopenings of Initial Determinations, Redeterminatons, Reconsiderations, Hearings and Reviews

The Interim Final Rule implements the new statutory provision to allow reopening to correct minor, technical and/or clerical errors. In addition, CMS establishes rules for reopening that are similar to current rules: 1 year for reopening without cause; 4 years for requesting or initiating a reopening for good cause, and at any time on claim determinations that have been procured through fraud or similar fault.

AHCA supports the new rule for reopenings to correct minor errors. As CMS has acknowledged, AHCA requests additional education of interested parties and clarification on the types of minor, technical and/or clerical errors that can be corrected through reopening. AHCA is hopeful that this process can eliminate the number of claims that have to be appealed.

I. Expedited Access to Judicial Review

The Interim Final rule allows a direct appeal to court where a review entity certifies that the appellant can show that there are no material facts in dispute, and that the MAC dos not have the authority to decide the question of law or regulations relevant to the maters in dispute. *See* 405. 990(a)(2). In practice, this will typically involve a challenge to the constitutionality of a statutory provision or the constitutionality or validity of a regulation or of a NCD. This is similar to the process previously only allowed for Medicare Part A cases under the jurisdiction of the Provider Reimbursement Review Board ("PRRB"). AHCA has been a long-time advocate for creating an avenue for expedited judicial review, and is pleased to see the provision included as part of the Interim Final Rule.

J. ALJ Hearings

In accordance with the statutory changes in the MMA, under the Interim Final Rule, ALJs will be under the jurisdiction of the Department of Health and Human Services ("HHS"), rather than the SSA. ALJs are expected to continue to function as independent adjudicators, although they may give substantial deference to CMS policy. ALJs will be required to conduct hearings by video teleconferencing ("VTC"), unless the technology is not available in the parties' location. Telephone hearings will be an option available to the parties. The appellant can request an in-person hearing, which will be granted upon a finding of good cause, but the 90-day time frame for holding the hearing and rendering a decision will be waived. Good cause exists if VTC technology is not available or special or extraordinary circumstances exists (*e.g.*, the case involves complex, challenging or novel issues). A party can only object to a VTC or telephone hearing with respect to its own testimony, not with respect to the entire hearing.

As with reconsiderations, under the Interim Final Rule, CMS provides that ALJs are to give substantial deference to an NCD, LCD, LMRP, and CMS program guidance;

the applicability of a NCD, LCD, LMRP, or CMS policy in a particular case may be raised at the request of a party or at the ALJ's discretion; and the ALJ may decline to follow a policy in a particular case, but must explain why. These decisions are case-specific and do not have precedential effect. As with QICs, if an ALJ fails to issue timely decision, the appellant may request that the case be escalated to the MAC.

AHCA recognizes that some beneficiary and provider organization have raised concerns about the potential conflict of interest of having ALJs hearing Medicare appeals within HHS. There is a legitimate apprehension about ALJs maintaining their independence and impartiality in adjudicating Medicare claims appeals if they are within the same federal agency that ultimately is paying the claim. On balance, however, AHCA believes that the benefits of having a cadre of trained and knowledgeable ALJs on the complexities of the Medicare program and its various payment systems outweigh the concern over impartiality. Still, AHCA recommends that HHS monitor this new structure and provide a complaint mechanism for appellants who believe that an ALJ has failed to maintain his or her independent judgment. Also, we recommend that CMS be more explicit as to how the ALJs will be trained on the specifics of the various Medicare payment systems. AHCA welcomes the opportunity for provider and beneficiary input into these training sessions, and requests that the training materials be made available to the public.

With respect to the conduct of the ALJ hearing, AHCA supports the use of VTC and telephone hearings for most cases to reduce travel costs for appellants and reduce the time frames for holdings hearings and rendering decisions within 90 days. However, AHCA strongly disagrees with the provision proposing to waive the 90-day time frame if the appellant can show good cause for in-person hearing due to complex case or issue of first impression. The significant reduction in the number of in-person hearings before an ALJ with the implementation of these new appeals procedures should permit ALJs to meet the 90-day time frame for the limited number of cases they hear in-person. Further, these complex appeals are often the ones that involve the most reimbursement and for which appellants are willing to devote the most resources to pursue (including, perhaps, expert testimony). Therefore, if the ALJ agrees that the case merits special treatment for an in-person hearing, it is even more important for the ALJ to hold a timely hearing and render a timely opinion. Alternatively, we believe CMS could establish a slightly longer, but still defined, time-frame for these complex appeals, such as 120 days to hear and decide the case.

With respect to holding hearings at 4 designated offices, we recognize the need for efficiency and streamlined operations to meet deadlines, but believe this should be closely monitored to ensure that it does not impede beneficiary, provider and supplier access to appeals.

Some commenters have raised questions in the past on participation by CMS and contractors in ALJ appeals. Our members' experience has been that this currently occurs on a *de facto* basis with certain ALJ hearings, and has not presented a

problem, provided that CMS and the contractors are not parties to the appeal and therefore do not have full party status. Their participation in the appeals process should be limited to answering questions from the appellant or the ALJ concerning the factual or underlying legal basis for the initial determination.

Finally, we urge CMS to state that ALJ decisions are entitled to substantial deference by other adjudicators in the appeals process. Cases that reach the ALJ level of review have already gone through three levels of review, and they are more likely to be the cases of most importance to beneficiaries and providers. When other parties have advocated their position and an ALJ has already fully considered an issue, it makes sense for others to have the benefit of the prior decisions and accord them substantial deference, similar to that which a district court accords to the other district courts within the same circuit. We think this rule would help to focus issues for appeals and streamline subsequent decisions.

K. Appeals Involving Overpayments

Under the Interim Final Rule, if an appeal from a QIC involves an overpayment issue and the QIC relies on a statistical sample in reaching a decision, the ALJ must base his or her decision on a review of all claims in the same statistical sample.

AHCA commends CMS for adopting this specific rule. AHCA also requests that CMS clarify that appellants may challenge the statistical methodology used by the contractor to select the statistical sample at any level of appeal, including at the QIC and ALJ levels, and that appellants be given all documentation concerning each phase of the contractor's sampling process as a matter of course.

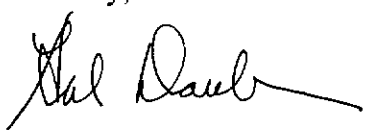
L. Review by the MAC and Judicial Review

Under the final rule, in accordance with the BIPA amendments, the MAC is a *de novo* review. The Interim Final Rule also provides for escalation to federal district court if the MAC does not issue a timely decision. In other respects the rule continues current policy on MAC reviews. AHCA supports these provisions, but reiterates the potential need to introduce new evidence that might only become pertinent following the ALJ's decision. This is particularly true since CMS can introduce new evidence at any time.

* * * *

Again, AHCA wishes to reiterate that we support the vast majority of the changes to the Medicare appeals process. We recognize the major challenges involved in this undertaking, and would be pleased to work with CMS, representatives of Medicare contractors, beneficiary groups and other interested parties to ensure a smooth transition to the new system and to address any logistical or operational issues that may arise.

Sincerely,



Hal Daub
President and CEO

Submitter : Ms. Vicki Gottlich **Date:** 05/09/2005

Organization : Center for Medicare Advocacy

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Dr. Harold Glickman **Date:** 05/09/2005

Organization : American Podiatric Medical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4064-IFC-17-Attach-1.DOC

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

May 9, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

RE: CMS-4064-IFC
Comments on Medicare Program; Changes to the Medicare Claims Appeal Procedures; Interim Final Rule (70 Fed. Reg. 11420, March 8, 2005)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA) is generally supportive of the changes to the Medicare claims appeal procedures in the interim final rule. Medicare beneficiaries, providers, suppliers, and physicians should have an equitable process to challenge Medicare decisions about individual or groups of claims. As the national association representing more than 11,000 doctors of podiatric medicine, the APMA offers the following comments:

Appeals Rights – Basis and Scope (70 Fed. Reg. 11427)

The APMA appreciates that CMS has specified that participating providers, beneficiaries, and suppliers (including physicians) who accept assignment all have the option to appeal a claim. It is important for all parties to be able to assert or defend their rights.

Redeterminations, Notifications, and Subsequent Limitations on Evidence (70 Fed. Reg. 11441)

The APMA recognizes that multiple notices to beneficiaries about overpayments, underpayments, and recoveries can be confusing and can create a false impression about the quality of services provided. Thus, APMA agrees with CMS that contractors should issue written notices about appeals only to the appellants.

Conduct of a Reconsideration (70 Fed. Reg. 11446)

The APMA appreciates that CMS will require the qualified independent contractors to use a panel of physicians or other health care professionals to reconsider issues of medical necessity. Such determinations should be based on clinical experience, medical records, and medical,

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scientific, and technical evidence. The APMA also believes that the reviewing physicians or health care professionals must have relevant expertise in the specialty or area of medicine involved in the appeal.

ALJ Hearings (70 Fed. Reg. 11454)

As these changes take effect, the APMA asks CMS to ensure that all rights and remedies are available in a timely fashion. The APMA is concerned about delays resulting from moving administrative law judges who review Medicare claims from the Social Security Administration to the Department of Health and Human Services. The APMA is also concerned that the reliance on videoteleconference hearings may be premature.

Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

Harold B. Glickman DPM

Harold B. Glickman, DPM
President

9312 Old Georgetown Road Bethesda, Maryland 20814-162
(301) 571-9200 Fax (301) 530-2752 http://www.apma.org

Submitter : Mr. William Dombi **Date:** 05/09/2005

Organization : National Association for Home Care and Hospice, In

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-18-Attach-1.DOC

Cmt#18

May 9, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4064-IFC
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., SW
Washington, D.C. 20201

RE: Medicare Program; Changes to Medicare Claims Appeals Procedures
CMS-4064-IFC
RIM0938-AM73

Thank you for the opportunity to provide comments on the interim final rule with comment. Regarding changes to the Medicare claims appeal procedures that set out in volume seventy (70) of the Federal Register on March, 8, 2005 beginning at page 11420. The following are the comments of the National Association for Home Care and Hospice, Inc (NAHC). NAHC is the largest trade association representing interests of home health agencies and hospices nationwide. With many of members of NAHC providing services under Medicare, the appeal procedure changes outlined in the rule are of significant interest.

These comments are set out into two sections: First, General Comments setting out overall impression of the rule; Second, Specific Comments on detailed comments of a particular regulation.

General Comments

Overall, the interim final rule presents a promulgation of procedures reasonably consistent with statutory mandates set out in the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (BIPA), P.L. 106.554 and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. 108-173.

The institution of appeal decision making time frames with the flexibility to recognize individual case specific needs related to evidence submission, scheduling of face to face hearings, and the opportunity to respond to CMS involvement in a appeal represents a strong improvement over current procedures. In addition, the institution of Medicare specific appeal procedures in substitution of the ill-fitting Social Security Administration appeal rules is extremely welcomed.

NAHC strongly supports the CMS decision to provide direct rights of appeals to home health agencies, hospices and other providers of Medicare services. This change offers a real opportunity for due process to the entities that are often the party directly impacted by an adverse claim determination. With the availability of direct appeal rights, providers of services will no longer need to pursue appeals as the appointed representative of the Medicare beneficiary and can reasonably continue to pursue those appeals after the death of the Medicare claimant. The direct provider appeal rights also should benefit the Medicare program at large through the efficiency gained by allowing the party with the direct interest at steak to take a direct route toward resolution of a coverage grievance.

While not directly addressed in the rule, NAHC remains cautious relative to the transition of hearing responsibilities to Administrative Law Judges (ALJ) under the US Department of Health and Human Services from the long standing arrangement with the Social Security Administration. Of particular concerns are the reports of limited locations of the ALJ's throughout the country, a situation that may impact on the availability and speed of face to face hearings. Since the rule on appeal procedures effectively exempts most face to face hearings from the designated time frames from decision making, the limited geographic location of the ALJ's may be a serious problem.

NAHC is also concerned about the lack of information regarding the training and support of the ALJ's. Recent inquiries from NAHC to HHS regarding the training of ALJ's have been referred to the Public Affairs Office at CMS. This is of concern since the ALJ's are required to be independent of CMS.

Specific Comments

Following are our specific comments directed to particular regulations. Where appropriate, NAHC offers a recommendation for amendment of that regulation.

Section 405.910 Appointed Representatives

Under subsection (d)(1), the rule requires the adjudicator to contact the party and provide a description of any missing documentation or information to allow the curing of a defective appointment of representatives. However, NAHC is unable to find any rule that correlates that curing opportunity with the time deadline for finalizing an appeal.

Recommendation: Amend the appropriate rule to specifically provide that an appeal that is filed within time limits remains timely where the only technical flaw is a defective appointment of representative that can and is cured.

Under subsection (e)(1), the rule states that an appointment is considered valid for one year .Subsection (e)(2) indicates that the appointment is valid for the duration of an appeal when that appeal is filed within the one (1) year time frame.

Recommendation: Modify subsection (e)(1) to state that an appointment is considered valid for one (1) year form the date of completion "except as provided in subsection (e)(2)." In addition, specifically state that an appointment of representative can be made before the issuance of an initial determination.

In subsection (g)(1)(v), the rule indicates that an appointed representative has an affirmative duty to comply with all CMS instructions.
Recommendation: Strike the references to "instructions" as those instructions do not have the force and effect of law and should not be binding on a representative any more than the instructions are binding upon a beneficiary, contractor, or administrative law judge.

Section 405.924 Actions that are initial determinations
Subsection (b)(7) references the number of home health visits used as an initial determination. This reference appears to be a hold over from a time when the number of visits used where relevant to whether the home health services where covered under Medicare Part A or Part B.

Recommendation: Strike subsection (b)(7).

Section 405.926

Under subsection (c) it provides that the computations of the payment amount of program reimbursement of general applicabilityare not considered an initial determination and, therefore, is not subject to an appeal. Since this subsection references the concept of "payment amount" it raises the question as to whether the "payment amount" of specific, individual claim applicability is considered an initial determination. Section 405.924 (b) does not include a payment amount as an initial determination. Instead, if references the "amount of benefits."

Recommendation: Amend sections 405.924 and 405.926 to specifically list the individual determinations on the "payment amount" as initial determinations. Section 405.926 should include an additional reference to an action that is not an initial determination with respect to a provider's notice of non-coverage to the Medicare beneficiary. While the provider of services may be the first decision-maker regarding Medicare coverage of an item or service, its notice of non coverage has not been considered on initial determination subject to appeal.

Section 405.946 Evidence to be submitted with the redetermination request.

In subsection (b, it provided that resubmission of additional evidence after filing the request of redetermination automatically extends the decision making time frame for fourteen (14) calendar days for each submission. The extension of the decision making time frame does not distinguish between evidentiary submissions initiated be a party and those in response to a request from the Medicare contractor.

Recommendation: The automatic extension of the decision making time frame should apply only for party initiated submissions. Where additional evidence is submitted in response to a request from the Medicare contractor, the time frames should remain in effect without any extension in order to prevent any abuses by the Medicare contractor.

Section 405.948 Conduct of a redetermination
This rule provides that a Contractor may raise and develop new issues that are relevant in a claim in a particular case. However, the rule provides no process for notifying the appellant for those new issues. In addition, there's no indication that the appellant has the opportunity to submit evidence or argument on those new issues.

Recommendation: The rule should provide that the Contractor notify the appellant and provide an opportunity to respond to any new issues raised by the Contractor.

Section 405.966 Evidence to be submitted with the reconsideration request

In subsection (a)(2), it provides that failure to submit all evidence precludes subsequent consideration of that evidence in the absence of good cause. NAHC generally objects to the restriction contained throughout the regulations on the submission of evidence and the obligation to establish good cause for any evidence a party seeks to submit at some point later than the notice of reconsideration.

In subsection (b), it provides that the automatic extension for the decision making time frame does not apply to timely submission of documentation specifically requested by QIC. This same standard should apply to the Medicare contractor responsible for the redetermination.

Section 405.968 Conduct of a reconsideration

In subsection (a) it provides that when a QIC's reconsideration involves a finding of whether a service is reasonable and necessary it must be considered by a panel of physicians or other appropriate healthcare professionals. It should be noted that there are other determinations that require healthcare expertise such as terminal illness status of a hospice benefit claimant, whether a home health patient is "confined at home" and whether a home health patient is receiving "intermittent skilled" care.

In addition, the rule generically refers to a panel of "physicians" or other appropriate healthcare professionals. That generic reference does not recognize that not all physicians are competent to judge the medical necessity of all services potentially covered under the Medicare program.

Recommendation: Revised subsection (a) to address the other healthcare related decisions that should be subject to professional review. Further, revise (a) with a reference to a panel of "appropriate physicians."

In subsection (b)(2), it provides that the QIC's must give "substantial deference" to CMS or Contractor policies while allowing the QIC to decline to follow a policy in a particular case. NAHC generally objects to the requirement that decision makers provide substantial deference to any policies that are not developed without full adherence to the notice and comment procedures of the Administrative Procedures Act. The allowance of substantial deference places a party in a position to prove the invalidity of a policy that had never been subject to any public scrutiny before its implementation. A "substantial deference" standard is nearly identical to the deferential standard granted to rules promulgated consistent with the APA under a long line of rulings form the US Supreme Court.

Recommendation: Remove any and all references at all stages of the appeals process to the provision of "substantial deference" to CMS or contractor polices and instructions.

In subsection (b)(5), it provides that a QIC may raise and develop new issues provided that the contractor rendered a redetermination with respect to claims. It is difficult to understand how a new issue could develop if a contractor has rendered a redetermination with respect to the claims. No reconsideration right exists unless there has been a redetermination with respect to the claim.

Recommendation: Modify the language consistent with other rules referencing the raising of new issues.

Section 405.970

In subsection(b)(2), the rule indicates that the QIC must issue a reconsideration decision within sixty (60) days of the latest filed request when multiple parties pursue an appeal. This standard places the first appellant at a disadvantage in a decision making time frame. While it is recognized that appeals submission from multiple parties may complicate decision making for the QIC, NAHC suggests that CMS modify this rule so that the last appeal filing party does not control the process for all appellants that came before that party.

Recommendation: Amend subsection (b)(2) to provide that the decision making time frame be extended by no more than fourteen (14) days from the deadline otherwise applicable to the original reconsideration request filing and that the fourteen (14) day

extension is applicable only if later party appeal request are submitted with new relevant evidence.

Section 405.980 Reopenings of initial determinations, redeterminations, reconsideration, hearings and reviews.

This rule provides that a Contractor must process redetermination requests involving minor errors or omissions as reopening rather than appeals. However, the rule does not adequately address the situation where the Contractor declines to reopen a matter that it labeled as a minor error or omission type. There is concern in the timing of its refusing to reopen if it extends beyond the time frame for filing an appeal.

Recommendation: Amend section 405.980(a)(3) to provide that a timely filed redetermination request that is treated as a reopening by the Contractor is reinstated as an appeal if the Contractor declines to reopen the matter or, upon reopening, does not issue a determination fully favorable to the appellant.

Further, NAHC recommends that where a Contractor receives a reopening request and disagrees that the issue is a clerical error, an appeal can be filed within sixty (60) days time frame for requesting reconsideration.

In subsection (b)(3) the rule provides that an initial determination can be reopened by the contractor if it was procured by fraud or "similar fault." NAHC is concerned that Medicare Contractors may reopen a claim at any time based on its review of the claim in any detail for the first time. For example, NAHC members have experienced claim review beyond the one (1) year time frame for reopening. Contractors argue that the claim had never undergone full record review previously. NAHC believes that this action meets neither a "good cause" standard or a "similar fault" standard.

Recommendation: Refine the definition of "good cause" under section 405.986 and "similar fault" under section 405.902 to prohibit the reopening of a claim after one (1) year from the date of the initial determination or redetermination if the sole claimed bases for reopening is an original review of documentation that existed at the time initial determination or redetermination was made.

Section 405.1000

On a general basis, NAHC objects to the allowance of participation or party status for CMS or its Contractors. In addition, the CMS response to NAHC's earlier comment that fees should be payable to a prevailing appellant in cases where CMS or its Contractors proceed with party status requires further clarification.

Section 405.1010 and 405.1012 When CMS or its Contractors may participate or be a party to a hearing.

It is unclear in theses rules as to whether CMS or its Contractor may submit documentary evidence when acting as a participant or party in an appeals. Further, it is unclear as to whether other parties will have opportunity to respond and whether such process authorizes a change in the decision making deadline.

Recommendation: 405.1010 and 405.1012 should be modified to prohibit the submission of any documentary evidence when CMS or its Contractors, acting as a participant or a party, have had that opportunity at the time of the redetermination request. In addition, in the event that the submission of documentary evidence is allowed in the final rule, there should be an opportunity for other parties to respond without a delay in the decision making time frame in that matter.

Section 405.1032 Issues before an ALJ

Subsection (b) appears to allow an ALJ to consider new issues raised from the participation of CMS at the ALJ level of adjudication in any of the evidence and position papers submitted by CMS for the first time to the ALJ. If this interpretation is accurate, allowing the consideration of new issues raised by CMS at the ALJ level of adjudication can operate as the equivalent of reopening a final decision that CMS or its Contractors had previously made. That effective reopening should not be allowed to occur if the matter could not have been reopened under section 405.980.

Recommendation: The rule should be amended to specify that no new issue should be addressed by the ALJ unless the standards for reopening are met.

Section 405.1037 Discovery

Subsection (b)(3) prohibits the use of admissions and interrogatories in an ALJ hearing. However, these discovery devices have proven to be very efficient in judicial proceedings

Recommendation: The use of admissions and interrogatories should be allowable under section 405.1037 under standards consistent with those applicable to the use of depositions.

Section 405.1062 Applicable local coverage determinations and other policies not binding on the ALJ and MAC.

As stated in the earlier General Comments, NAHC objects to providing substantial deference to policy guidance such as program memorandum and manual instructions. However, if the final rule continues this allowance, the rule should provide a definition of "substantial deference."

Recommendation: Suspend the authority to rely upon CMS or Contractor policy until a definition of "substantial deference" is promulgated.

Section 405.1064 ALJ decisions involving statistical samples

This regulation provides that an ALJ must base a decision on a review of the entire statistical sample. The rule does not address the ALJ authority to review challenges to sampling methodology in addition to any decision on the claim sampled.

Recommendation: Amend 405.1064 to specifically provide for ALJ authority to address challenges to the sampling methodology.

Section 405.1100

This rule provides that the Medicare Appeals Council undertakes De Novo review of an ALJ decision. However, other MAC rules limit opportunity for face to face hearings and provide restricted opportunity for the submission of evidence. As such, a De Novo review is not warranted.

Recommendation: Modify subsection (c) to provide for "substantial evidence" standard of review as is applicable in judiciary review. Alternatively, utilize a "preponderance of evidence" as set out in section 405.1110.

Section 405.1136 Judicial Review

In subsection (b), the rule provides that a civil action must be filed in a district court of the United States for the judicial district in which the party resides or where such individual, institutions, or agency has its primary place of business. The rule does not state that a civil action can be filed in Washington, D.C. or the location of the regional offices of HHS.

Recommendation Specifically state that a civil action can be filed in Washington, D.C. or the judicial district in which a regional office of HHS exists.

Conclusion

Thank you for the opportunity to submit these comments.

Very truly yours,

William A. Dombi
Vice President of Law

Submitter : **Ms. Dawn Mancuso** **Date: 05/09/2005**

Organization : **Association of Air Medical Services (AAMS)**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : **Mr. William Dombi** **Date: 05/09/2005**

Organization : **National association for Home Care and Hospice**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-20-Attach-1.DOC

Cmt#20

May 9, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4064-IFC
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave., SW
Washington, D.C. 20201

RE: Medicare Program; Changes to Medicare Claims Appeals Procedures
CMS-4064-IFC
RIM0938-AM73

Thank you for the opportunity to provide comments on the interim final rule with comment. Regarding changes to the Medicare claims appeal procedures that set out in volume seventy (70) of the Federal Register on March, 8, 2005 beginning at page 11420. The following are the comments of the National Association for Home Care and Hospice, Inc (NAHC). NAHC is the largest trade association representing interests of home health agencies and hospices nationwide. With many of members of NAHC providing services under Medicare, the appeal procedure changes outlined in the rule are of significant interest.

These comments are set out into two sections: First, General Comments setting out overall impression of the rule; Second, Specific Comments on detailed comments of a particular regulation.

General Comments

Overall, the interim final rule presents a promulgation of procedures reasonably consistent with statutory mandates set out in the Medicare, Medicaid and SCHIP Benefits Improvement Protection Act of 2000 (BIPA), P.L. 106.554 and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. 108-173.

The institution of appeal decision making time frames with the flexibility to recognize individual case specific needs related to evidence submission, scheduling of face to face hearings, and the opportunity to respond to CMS involvement in a appeal represents a strong improvement over current procedures. In addition, the institution of Medicare specific appeal procedures in substitution of the ill-fitting Social Security Administration appeal rules is extremely welcomed.

NAHC strongly supports the CMS decision to provide direct rights of appeals to home health agencies, hospices and other providers of Medicare services. This change offers a real opportunity for due process to the entities that are often the party directly impacted by an adverse claim determination. With the availability of direct appeal rights, providers of services will no longer need to pursue appeals as the appointed representative of the Medicare beneficiary and can reasonably continue to pursue those appeals after the death of the Medicare claimant. The direct provider appeal rights also should benefit the Medicare program at large through the efficiency gained by allowing the party with the direct interest at steak to take a direct route toward resolution of a coverage grievance.

While not directly addressed in the rule, NAHC remains cautious relative to the transition of hearing responsibilities to Administrative Law Judges (ALJ) under the US Department of Health and Human Services from the long standing arrangement with the Social Security Administration. Of particular concerns are the reports of limited locations of the ALJ's throughout the country, a situation that may impact on the availability and speed of face to face hearings. Since the rule on appeal procedures effectively exempts most face to face hearings from the designated time frames from decision making, the limited geographic location of the ALJ's may be a serious problem.

NAHC is also concerned about the lack of information regarding the training and support of the ALJ's. Recent inquiries from NAHC to HHS regarding the training of ALJ's have been referred to the Public Affairs Office at CMS. This is of concern since the ALJ's are required to be independent of CMS.

Specific Comments

Following are our specific comments directed to particular regulations. Where appropriate, NAHC offers a recommendation for amendment of that regulation.

Section 405.910 Appointed Representatives

Under subsection (d)(1), the rule requires the adjudicator to contact the party and provide a description of any missing documentation or information to allow the curing of a defective appointment of representatives. However, NAHC is unable to find any rule that correlates that curing opportunity with the time deadline for finalizing an appeal.

Recommendation: Amend the appropriate rule to specifically provide that an appeal that is filed within time limits remains timely where the only technical flaw is a defective appointment of representative that can and is cured.

Under subsection (e)(1), the rule states that an appointment is considered valid for one year .Subsection (e)(2) indicates that the appointment is valid for the duration of an appeal when that appeal is filed within the one (1) year time frame.

Recommendation: Modify subsection (e)(1) to state that an appointment is considered valid for one (1) year form the date of completion "except as provided in subsection (e)(2)." In addition, specifically state that an appointment of representative can be made before the issuance of an initial determination.

In subsection (g)(1)(v), the rule indicates that an appointed representative has an affirmative duty to comply with all CMS instructions.
Recommendation: Strike the references to "instructions" as those instructions do not have the force and effect of law and should not be binding on a representative any more than the instructions are binding upon a beneficiary, contractor, or administrative law judge.

Section 405.924 Actions that are initial determinations
Subsection (b)(7) references the number of home health visits used as an initial determination. This reference appears to be a hold over from a time when the number of visits used where relevant to whether the home health services where covered under Medicare Part A or Part B.

Recommendation: Strike subsection (b)(7).

Section 405.926

Under subsection (c) it provides that the computations of the payment amount of program reimbursement of general applicabilityare not considered an initial determination and, therefore, is not subject to an appeal. Since this subsection references the concept of "payment amount" it raises the question as to whether the "payment amount" of specific, individual claim applicability is considered an initial determination. Section 405.924 (b) does not include a payment amount as an initial determination. Instead, if references the "amount of benefits."

Recommendation: Amend sections 405.924 and 405.926 to specifically list the individual determinations on the "payment amount" as initial determinations. Section 405.926 should include an additional reference to an action that is not an initial determination with respect to a provider's notice of non-coverage to the Medicare beneficiary. While the provider of services may be the first decision-maker regarding Medicare coverage of an item or service, its notice of non coverage has not been considered on initial determination subject to appeal.

Section 405.946 Evidence to be submitted with the redetermination request.

In subsection (b, it provided that resubmission of additional evidence after filing the request of redetermination automatically extends the decision making time frame for fourteen (14) calendar days for each submission. The extension of the decision making time frame does not distinguish between evidentiary submissions initiated be a party and those in response to a request from the Medicare contractor.

Recommendation: The automatic extension of the decision making time frame should apply only for party initiated submissions. Where additional evidence is submitted in response to a request from the Medicare contractor, the time frames should remain in effect without any extension in order to prevent any abuses by the Medicare contractor.

Section 405.948 Conduct of a redetermination
This rule provides that a Contractor may raise and develop new issues that are relevant in a claim in a particular case. However, the rule provides no process for notifying the appellant for those new issues. In addition, there's no indication that the appellant has the opportunity to submit evidence or argument on those new issues.

Recommendation: The rule should provide that the Contractor notify the appellant and provide an opportunity to respond to any new issues raised by the Contractor.

Section 405.966 Evidence to be submitted with the reconsideration request

In subsection (a)(2), it provides that failure to submit all evidence precludes subsequent consideration of that evidence in the absence of good cause. NAHC generally objects to the restriction contained throughout the regulations on the submission of evidence and the obligation to establish good cause for any evidence a party seeks to submit at some point later than the notice of reconsideration.

In subsection (b), it provides that the automatic extension for the decision making time frame does not apply to timely submission of documentation specifically requested by QIC. This same standard should apply to the Medicare contractor responsible for the redetermination.

Section 405.968 Conduct of a reconsideration

In subsection (a) it provides that when a QIC's reconsideration involves a finding of whether a service is reasonable and necessary it must be considered by a panel of physicians or other appropriate healthcare professionals. It should be noted that there are other determinations that require healthcare expertise such as terminal illness status of a hospice benefit claimant, whether a home health patient is "confined at home" and whether a home health patient is receiving "intermittent skilled" care.

In addition, the rule generically refers to a panel of "physicians" or other appropriate healthcare professionals. That generic reference does not recognize that not all physicians are competent to judge the medical necessity of all services potentially covered under the Medicare program.

Recommendation: Revised subsection (a) to address the other healthcare related decisions that should be subject to professional review. Further, revise (a) with a reference to a panel of "appropriate physicians."

In subsection (b)(2), it provides that the QIC's must give "substantial deference" to CMS or Contractor policies while allowing the QIC to decline to follow a policy in a particular case. NAHC generally objects to the requirement that decision makers provide substantial deference to any policies that are not developed without full adherence to the notice and comment procedures of the Administrative Procedures Act. The allowance of substantial deference places a party in a position to prove the invalidity of a policy that had never been subject to any public scrutiny before its implementation. A "substantial deference" standard is nearly identical to the deferential standard granted to rules promulgated consistent with the APA under a long line of rulings form the US Supreme Court.

Recommendation: Remove any and all references at all stages of the appeals process to the provision of "substantial deference" to CMS or contractor polices and instructions.

In subsection (b)(5), it provides that a QIC may raise and develop new issues provided that the contractor rendered a redetermination with respect to claims. It is difficult to understand how a new issue could develop if a contractor has rendered a redetermination with respect to the claims. No reconsideration right exists unless there has been a redetermination with respect to the claim.

Recommendation: Modify the language consistent with other rules referencing the raising of new issues.

Section 405.970

In subsection(b)(2), the rule indicates that the QIC must issue a reconsideration decision within sixty (60) days of the latest filed request when multiple parties pursue an appeal. This standard places the first appellant at a disadvantage in a decision making time frame. While it is recognized that appeals submission from multiple parties may complicate decision making for the QIC, NAHC suggests that CMS modify this rule so that the last appeal filing party does not control the process for all appellants that came before that party.

Recommendation: Amend subsection (b)(2) to provide that the decision making time frame be extended by no more than fourteen (14) days from the deadline otherwise applicable to the original reconsideration request filing and that the fourteen (14) day

extension is applicable only if later party appeal request are submitted with new relevant evidence.

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This rule provides that a Contractor must process redetermination requests involving minor errors or omissions as reopening rather than appeals. However, the rule does not adequately address the situation where the Contractor declines to reopen a matter that it labeled as a minor error or omission type. There is concern in the timing of its refusing to reopen if it extends beyond the time frame for filing an appeal.

Recommendation: Amend section 405.980(a)(3) to provide that a timely filed redetermination request that is treated as a reopening by the Contractor is reinstated as an appeal if the Contractor declines to reopen the matter or, upon reopening, does not issue a determination fully favorable to the appellant.

Further, NAHC recommends that where a Contractor receives a reopening request and disagrees that the issue is a clerical error, an appeal can be filed within sixty (60) days time frame for requesting reconsideration.

In subsection (b)(3) the rule provides that an initial determination can be reopened by the contractor if it was procured by fraud or "similar fault." NAHC is concerned that Medicare Contractors may reopen a claim at any time based on its review of the claim in any detail for the first time. For example, NAHC members have experienced claim review beyond the one (1) year time frame for reopening. Contractors argue that the claim had never undergone full record review previously. NAHC believes that this action meets neither a "good cause" standard or a "similar fault" standard.

Recommendation: Refine the definition of "good cause" under section 405.986 and "similar fault" under section 405.902 to prohibit the reopening of a claim after one (1) year from the date of the initial determination or redetermination if the sole claimed bases for reopening is an original review of documentation that existed at the time initial determination or redetermination was made.

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Section 405.1010 and 405.1012 When CMS or its Contractors may participate or be a party to a hearing.

It is unclear in theses rules as to whether CMS or its Contractor may submit documentary evidence when acting as a participant or party in an appeals. Further, it is unclear as to whether other parties will have opportunity to respond and whether such process authorizes a change in the decision making deadline.

Recommendation: 405.1010 and 405.1012 should be modified to prohibit the submission of any documentary evidence when CMS or its Contractors, acting as a participant or a party, have had that opportunity at the time of the redetermination request. In addition, in the event that the submission of documentary evidence is allowed in the final rule, there should be an opportunity for other parties to respond without a delay in the decision making time frame in that matter.

Section 405.1032 Issues before an ALJ

Subsection (b) appears to allow an ALJ to consider new issues raised from the participation of CMS at the ALJ level of adjudication in any of the evidence and position papers submitted by CMS for the first time to the ALJ. If this interpretation is accurate, allowing the consideration of new issues raised by CMS at the ALJ level of adjudication can operate as the equivalent of reopening a final decision that CMS or its Contractors had previously made. That effective reopening should not be allowed to occur if the matter could not have been reopened under section 405.980.

Recommendation: The rule should be amended to specify that no new issue should be addressed by the ALJ unless the standards for reopening are met.

Section 405.1037 Discovery

Subsection (b)(3) prohibits the use of admissions and interrogatories in an ALJ hearing. However, these discovery devices have proven to be very efficient in judicial proceedings

Recommendation: The use of admissions and interrogatories should be allowable under section 405.1037 under standards consistent with those applicable to the use of depositions.

Section 405.1062 Applicable local coverage determinations and other policies not binding on the ALJ and MAC.

As stated in the earlier General Comments, NAHC objects to providing substantial deference to policy guidance such as program memorandum and manual instructions. However, if the final rule continues this allowance, the rule should provide a definition of "substantial deference."

Recommendation: Suspend the authority to rely upon CMS or Contractor policy until a definition of "substantial deference" is promulgated.

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This regulation provides that an ALJ must base a decision on a review of the entire statistical sample. The rule does not address the ALJ authority to review challenges to sampling methodology in addition to any decision on the claim sampled.

Recommendation: Amend 405.1064 to specifically provide for ALJ authority to address challenges to the sampling methodology.

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This rule provides that the Medicare Appeals Council undertakes De Novo review of an ALJ decision. However, other MAC rules limit opportunity for face to face hearings and provide restricted opportunity for the submission of evidence. As such, a De Novo review is not warranted.

Recommendation: Modify subsection (c) to provide for "substantial evidence" standard of review as is applicable in judiciary review. Alternatively, utilize a "preponderance of evidence" as set out in section 405.1110.

Section 405.1136 Judicial Review

In subsection (b), the rule provides that a civil action must be filed in a district court of the United States for the judicial district in which the party resides or where such individual, institutions, or agency has its primary place of business. The rule does not state that a civil action can be filed in Washington, D.C. or the location of the regional offices of HHS.

Recommendation Specifically state that a civil action can be filed in Washington, D.C. or the judicial district in which a regional office of HHS exists.

Conclusion

Thank you for the opportunity to submit these comments.

Very truly yours,

William A. Dombi
Vice President of Law

CMS-4064-IFC-21

Submitter : Ms. Amy Leopard **Date:** 05/09/2005

Organization : Great Lakes Law

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See attached letter concerning primarily issues 11-17

CMS-4064-IFC-21-Attach-1.DOC

GREAT LAKES LAW
HEALTH CARE GROUP

June 1, 2005

Submitted Electronically at http://www.cms.hhs.gov/regulations/ecomments

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: CMS-4064-IFC - Changes to the Medicare Claims Appeals Procedures

Dear Dr. McClellan:

On behalf of the Health Care Group of Great Lakes Law, we are pleased to submit the following comments on the Centers for Medicare and Medicaid Services ("CMS") interim final rule establishing new appeals procedures for Medicare Part A and Part B claims denials. See 70 Fed. Reg. 11420 (March 8, 2005) (the "Interim Claims Appeals Rule.")

Great Lakes Law is a strategic alliance that draws on the strengths of 12 firms and more than 1200 attorneys to provide for the legal needs of their clients beyond their respective jurisdictions. Great Lakes Law attorneys are located in the states of California, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Minnesota, New Jersey, New York, Ohio, Pennsylvania, Texas, Wisconsin and Washington D.C. as well as Canadian firms in Ontario and Quebec.

The Health Care Group members share their broad range of expertise and experience in the he alth c are indus try c lient ne eds, e xchange inf ormation, a nd ke ep c urrent r egarding ne w developments and trends among the member lawyers in the health care law specialty practice area. These attorneys have an interest in promoting the effectiveness of the Medicare appeals process and ensuring that while the workload demands are met in a timely fashion, the Medicare claims appeals system is accessible and fair for both beneficiaries and providers.

Comments on the Interim Claims Appeals Rule

The Interim Claims Appeals Rule seeks to implement the changes in the Medicare appeals process contemplated by Congress in Section 931 of Subtitle D of Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173 ("MMA") and the Medicare and Medicaid and Section 521 of the SCHIP Benefits Improvement Act of 2000, Pub. Law 106-554("BIPA"). The much needed changes envisioned by BIPA and MMA are in large part a response to concerns expressed by the industry and documented in numerous government reports that the current appeals process does not meet the needs of the Medicare program, its beneficiaries, and the providers who serve them.

We support the objective of streamlining the appeals process by consolidating Part A and Part B procedures and reducing the considerable backlog of appeals. We believe that the following recommendations contained in our comments will allow the Department of Health and Human Services to achieve its goals of timely appeals without compromising access to a full and fair consideration of the complex issues often involved in the adjudicatory process for Medicare claims appeals.

Most of our comments concern changes at the Administrative Law Judge Level, including the new evidentiary restrictions, the process for CMS to elect to participate in a hearing or act as a party, the limits on discovery, the substantial deference given to CMS informal policies, and the conduct of the hearing itself. In addition, we provide commentary on the changes envisioned with regard to judicial review and special issues not addressed in the rule, namely, the independence of the Administrative Law Judges and the geographic distribution of the ALJ offices.

Administrative Law Judge Level

1. Evidentiary Restrictions (405.966, 405.1018)

Under the Claims Appeals Rule, evidence not introduced at the QIC level cannot be introduced later at a higher level of appeal absent a showing of "good cause." This limitation may result in hardship to providers who do not have ready access to all relevant documentation within the short time frames applicable to the QIC level, such as records maintained by other providers, and limits the provider's ability to obtain expert reports. We recommend that evidence on new issues be permitted to be introduced at all levels.

The ALJ is to determine whether good cause exists, and the only guidance in the Rule is a single example, "An ALJ finds good cause, for example, when the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration." We believe that a broader definition of "good cause" should be adopted to take into account a variety of circumstances where relevant evidence may not be readily available to an appellant at the QIC level for reasons beyond the appellant's control; and to permit rebuttal evidence in response to CMS positions and evidence at all levels where CMS participates.

2. Conduct of the Hearing

Video teleconferencing is the default method under §405.1000 of the Rule. Appellants who wish a face-to-face hearing are subject to delays which can be financially catastrophic to small practices and entities, particularly when offsets of Medicare payments are in place. We believe that an appellant should be able to elect an in-person hearing at any time without delaying the scheduling of the hearing. Additionally, we question whether the three planned regional in- locations (Cleveland, Irvine, CA and Miami) will provide sufficient geographic access to those parties desiring an in-person ALJ hearing.

Further, videoconferencing may be an inadequate substitute for an in-person hearing. As many Medicare hearings turn on the interpretation of medical records where handwriting may be difficult to decipher, in-person hearings allow the parties and judge to examine the original

records whereas VTC only permits the introduction of imperfect copies. Witness credibility can be more thoroughly evaluated in person ensuring that providers and beneficiaries have their day in court.

Finally, we understand that Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and the committee's ranking Democrat, Max Baucus, question whether HHS has access to enough video teleconferencing units to give providers and beneficiaries speedy hearings.[1]

3. CMS Participation and Party Status in Appeals at the ALJ Level (405.1010, 405.1012)

§405.1010(a) provides that the ALJ may request the "participation" of CMS or a contractor in any ALJ hearing. The CMS commentary (70 FR 11459) justified that provision by asserting that "ALJs have requested [in prior hearings] position papers, testimony, or other evidence from CMS or a contractor," and observed that the process for doing so had been "cumbersome." The interim final rule, however, exceeds that rationale. It allows CMS or a contractor to "elect to participate" in the hearing process without ALJ request.

CMS did not offer any historical basis for self-initiated CMS participation in an ALJ hearing, particularly under the very limited non-party "participation" status outlined in §405.1010. One may only conclude that the goal of this rule is to respond to CMS's other observation, also in 70 FR 11459, that CMS and OIG "concluded that [certain prior payment appeal] cases might have been resolved more appropriately if CMS or the contractor had been party to the appeal." (emphasis supplied).

"Participation" is a way by which CMS or a contractor/QIC can initiate an adversarial action in an appeal, after the evidentiary record is virtually closed, without incurring the normal obligations of a party. Yet, CMS has not openly acknowledged any purpose to monitor issues in appeals and to influence selected ALJ hearings toward CMS-favored positions. Instead of advancing an unexplained agenda, CMS should restrict "participation" to those instances where the ALJs themselves, detecting gaps in the record presented by the appellant and QIC, seek to have specific information from CMS. It is especially remarkable, and distressing, that under the rule CMS or a contractor may implement "participation" even where an unrepresented claimant is the appellant.

§405.1010(c) asserts that CMS or the contractor will merely offer "position papers" or "testimony" "to clarify factual or policy issues in a case," while not "calling witnesses." In either case, the rule opens a door for CMS or contractor employees to place before the ALJ an unrestricted spread of administrative miscellany, anecdotal evidence and ad hoc rationalization, none of which is authoritative but, since it need not have appeared in the case before, all of which is a surprise to the appellant.

If CMS retains the unilateral privilege of self-initiated "participation" for itself and its contractors, certain reforms must be made. First, where CMS or a contractor actually offers testimony of an individual, the appellant must be allowed to cross examine that witness, contrary

[1] "ALJ teleconferences may put providers at a disadvantage," *Medicare Compliance Alert*, April 24, 2005; "Cleveland chosen as new site for Medicare appeals," *Cleveland Plain Dealer*, March 31, 2005.

to the current §405.1010(d), and any prior writings or testimonial transcripts by that individual must be produced. Since that could impose a substantial burden on CMS, it would be fair to allow CMS to withdraw the witness or to simply refuse the cross examination, but to allow the ALJ in the case of such a refusal to draw an adverse inference from it. That change would require modification of §405.1010(f).

Second, when CMS or a contractor elects to "participate" and to submit anything into the record, the record must be reopened to allow the appellant to refute the evidence, position paper or other material offered by CMS or the contractor. By definition (§405.1028), submission of post-QIC evidence or opinion by CMS or a contractor must be made "good cause" for appellants to respond, without ALJ discretion to refuse.

Third, §405.1010(c) should be limited to allow submission not of unrestricted "position papers," which may constitute simply written testimonial opinion, but of materials to which other rules require ALJs' adherence or deference, such as those listed in §405.1060-1063. A plausible case at least can be made for introducing ALJs to authoritative materials which a contractor or QIC might have overlooked, and a full set of authoritative materials could aid both appellants and CMS. The unrestricted right to offer "position papers" and "clarifying" testimony of CMS and contractor functionaries invites debasement of the hearing process, devaluing disciplined reason and elevating the individual views of officials of the contractor or CMS. A NCD or Administrator's decision that requires testimonial "clarification" or explanation of the agency "position" is not a sufficiently clear basis for denying a claim in the first place, and no such rationalization should be allowed.

The Interim Claims Appeal Rule also allows CMS to elect party status, making the appeal adversarial, a most significant change not authorized or contemplated by Congress. The rule for participating as a party at §405.1012(c) shares at least one defect with §405.1010, specifically the provision for CMS or a contractor to add to the record without a corresponding right on the part of appellants to answer that material, other than upon an ALJ finding of "good cause" And so defined in §405.1028. An ALJ hearing in which a government party has openly intervened is openly adversarial. The fundamental due process right to answer adverse evidence and testimony should be explicitly conferred by the rule, if the new appellate process is to gain the respect it should have.

4. Discovery Restrictions. (405.1037)

Under the Interim Claims Appeal Rule, discovery is available ONLY when CMS participates as a party, and extends the timeframes for decisions. Further, CMS cannot be called as a witness if it participates at a hearing. The current Medicare claims appeals process as outlined in the appeals procedures for the Social Security Administration are not responsible for the inordinate delays in Medicare appeals decisions. The restrictions on discovery ignore the fact that minimal due process entails the opportunity to confront one's accusers.

Documents should be discoverable, including anything relied upon by the carrier or previous decision maker, for the appellant to understand the basis and properly prepare a response, for example, by reviewing the auditors worksheets upon which denials are based.

Coupled with the issues presented above, beneficiaries and providers should be allowed to confront and cross examine witnesses against the claimant at any time. There is no legitimate reason to restrict document discovery, any evidence related to the denials or upon which denials were based, and to examine carrier personnel or QIC experts at the subsequent levels of appeal.

5. Substantial Deference Given to CMS and Carrier Policies (405.968(b), 405.1060, 405.1062, 405.1063)

Under the Interim Claims Appeal Rule, decision makers at all levels are required to give CMS policies greater deference than similar informal agency policies are typically granted within administrative appeal processes. This increased deference is particularly troubling in light of the transfer of the ALJs from the Social Security Administration to HHS, notwithstanding the obligations of HHS to ensure the independence of the ALJs.

With regard to informal agency decisions, ALJs and the MAC currently decide whether informal agency policies are entitled to deference based on Supreme Court precedents. Many informal CMS policies are used to deny Medicare claims, and these policies have not been promulgated in accordance with the notice-and-comment and Federal Register publication requirements of §1811(b)(1) of the Social Security Act and §553 of the Administrative Procedure Act.[2]

Currently, informal policies do not receive such special consideration as contemplated by the Interim Claims Appeal Rule. Rather, ALJs decide how much deference is due in a particular case based on the policy's power to persuade. The Supreme Court has established factors to consider in determining the deference accorded to informal agency manuals. The weight accorded to agency policy depends upon (1) the agency's care and thoroughness in considering the policy (2) the agency's consistency on the position, (3) the agency's formality in reaching the policy, (4) the relative expertness of the agency, (5) the validity of the agency's reasoning, (5) the formality of the policy, and (6) "all those factors which give it power to persuade." *U.S. v Mead Corp.*, 533 U.S. 218, 228 (2001), citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 139-140 (1944).

The substantial deference standard incorporated in the Interim Claims Appeal Rule essentially allows CMS to impose binding obligations on beneficiaries and providers without a public comment process. In order to establish the appearance and reality of a truly independent appeal process and a "level playing field" for both sides in a Medicare dispute, the QICs and ALJs must be able to review challenges to agency policies without a presumption of validity.

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[2] Section 1871(a)(1) of the Social Security Act, 42 U.S.C. §1395hh(a)(2), provides that "no rule, requirement, or other statement of policy . . . that establishes . . . a substantive legal standard governing . . . the payment for services [under Medicare] shall take effect unless it is promulgated by the Secretary [of HHS] by regulation." The Secretary must publish proposed regulations in the Federal Register and provide for a sixty-day comment period before becoming final. 42 U.S.C. §1395hh(b)(1) (also known as "notice and comment"). *See also* 5 U.S.C. §553 (Administrative Procedure Act requirements for agencies to follow when making binding rules).

6. Responsibilities of Appointed Representatives. (405.910 (g))

The Rule imposes an "affirmative duty" on appointed representatives, including attorneys, to "[c]omply with all laws and CMS regulations, CMS Rulings, and instructions." It is not uncommon for an attorney or other representative of a provider to challenge the validity of CMS rulings, policies, instructions and other interpretations as inconsistent with applicable law and regulation. It is unreasonable to require a representative to defer to all such policies to the potential determent of the provider/appellant. Further, it is inconsistent with the Rule's statements that ALJ and MAC decisions have no precedential effect.[3]

7. Judicial Review – 405.1136(f)

Under the standards set for at for Federal District Court review, a finding of the Secretary as to any fact, if supported by substantial evidence is deemed conclusive. If the decision is adverse due to failure to submit documentation under a regulation for payment, the court will review only whether the proof conforms to the regulation and the validity of the regulation. This standard restricts federal judges from applying the Administrative Procedures Act and evolving doctrines of judicial review of administrative decisions that govern other agencies.

8. Special Concerns not addressed in the Rule

a. Geographic Distribution of ALJ Offices

We are concerned about the reduction of in-person sites from numerous local Social Security offices to only three regional offices (Cleveland, Miami and Irvine, CA). Limiting in-person hearings to those locations will force many litigants to use the imperfect VTC substitute rather than incur the expense, lost income and inconvenience of traveling to one of these locations with attorneys and witnesses.

More critically, we are aware of reports that a large percentage of the existing veteran SSA ALJs who have been offered positions at these three regional locations are declining to relocate. The loss of the "institutional memory" and skills of a cadre of experienced, knowledgeable and sophisticated ALJs who have handled Medicare appeals for years will be to the detriment of all parties. The issues involved in Medicare appeals are frequently highly technical and complex, and litigants may increasingly need to educate new ALJs about the basics of the underlying regulatory environment as a preliminary matter before addressing the disputed issues.

b. Independence of Administrative Law Judges

Under BIPA and MMA, the ALJ office must be organizationally and functionally separate from CMS, reporting directly to the HHS Secretary. In short, the ALJs and the MAC must be free from influence by or guidance from CMS to be truly independent from CMS to provide an objective evaluation. The restrictions requiring deference to CMS, the participation

[3] 42 C.F.R. §405.1062(b)

by CMS, the restrictions on discovery, and the change to a more adversarial approach invite further Congressional action to maintain the independence contemplated by Congress.

HHS has not promulgated any rules nor elaborated upon how the new Office of Hearings and Appeals will function. Formalized procedures are necessary to ensure that the independence of ALJs is safeguarded and that the agency institutes precautions for maintaining the functional and physical integrity of ALJ independence with broad input from the industry.

The Health Care Group of Great Lakes Law supports the improvements to the Medicare claims appeals process and would be please to discuss these issues further with your staff. You may contact any of the following Great Lakes Law Health Care Group members:

Brian Kaser Foster, Swift, Collins & Smith, P.C.	bkaser@fosterswift.com (517) 371-8279
Amy Leopard Walter & Haverfield LLP	aleopard@walterhav.com 216-928-2889
William H. Maruca Fox, Rothschild LLP	wmaruca@foxrothschild.com 412-394-5575
Mary Ross Harter, Secrest & Emery LLP	mross@hselaw.com

cc: HHS Secretary Michael Leavitt
Senator Charles Grassley
Senator Max Baucus

Submitter : Mr. Eric Sokol **Date:** 05/09/2005

Organization : Power Mobility Coalition

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4064-IFC-22-Attach-1.DOC

The Power Mobility Coalition
WORKING TOGETHER FOR FREEDOM AND INDEPENDENCE

Cmt#22

June 1, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

RE: Comments to the Interim Final Rule Concerning Changes to the Medicare Appeals Process, CMS-4064-IFC

Dear Sir or Madam:

On behalf of the Power Mobility Coalition (PMC), a national association for manufacturers, suppliers, and beneficiaries of motorized scooters and power wheelchairs, we are submitting comments in response to the changes to the Medicare Appeals Procedures that has been published as an interim final rule in 70 Fed. Reg.11,420 -11,499 (Tuesday, March 8, 2005). The interim final rule is entitled "*Medicare Program: Changes to the Medicare Claims Appeals Procedures.*"

The PMC supports reforms to the Medicare Appeals Procedures that streamlines the process, provides statutorily finite timelines, respects the rights of beneficiaries and suppliers, and alleviates unnecessary administrative burdens on petitioners while maintaining balance, fairness, and justice in the system. To this end, the PMC has the following comments concerning the recently released interim final rule:

USE OF PATIENTS' MEDICAL RECORDS

Section 405.968(a) of the interim final rule states, in part, the following:

> If the initial determination involves a finding on whether an item or services is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's [Qualified Independent Contractor] reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

This regulation does not define "medical record" nor does it address specific items and services that require physician completion of a Certificate of Medical Necessity ("CMN").

Recommendation: The agency should clarify that the CMN is a medical record and that Congress established the CMN to demonstrate medical necessity. In fact, the CMN is defined by Congress as a "form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member."[1] The CMNs were developed by CMS and the medical community and have been approved and reapproved by the OMB.

When the CMNs were developed and approved by the OMB subject to formal public notice and comment, CMS stated the following in its 1996 PRA submission:

> For the CMNs which remain, the DMERC medical directors have determined the specific information needed to make a medical necessity determination. This information requires the application of medical judgment that can only be provided by a physician or other clinician who is familiar with the condition of the beneficiary.[2]

The content of the motorized wheelchair CMN has remained the same since initial approval in 1996.

The Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") reiterated the same theme in a fraud alert in 1999, entitled "*Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services,*" in which it stated:

> The Medicare program only pays for health care services that are medically necessary. In determining what services are medically necessary, Medicare primarily relies on the professional judgment of the beneficiary's treating physician, since he or she knows the patient's history and makes critical decisions, such as admitting the patient to the hospital; ordering tests, drugs, and treatments; and determining the length of treatment. In other words, the physician has the key role in determining the medical need for and utilization of, many health care services, including those furnished and billed by other providers and suppliers. Congress has conditioned payment for many Medicare items and services on a certification signed by a physician attesting that the item or service is medically necessary. For example, physicians are routinely required to certify to the medical necessity for any service for which they submit bills to the Medicare program.

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[1] Section 1834(j)(2) of the Social Security Act passed as part of the Social Security Act amendments of 1994.

[2] HCFA PRA Submission, *Durable Medical Equipment Regional Carrier, Certificates of Medical Necessity*, 5 (November 6, 1996).

> Physicians are also involved in attesting to medical necessity when ordering services, or supplies that must be billed and provided by an independent supplier or provider. Medicare requires physicians to certify to the medical necessity for many of these items and services through prescriptions, orders, or, in certain specific circumstances, Certificates of Medical Necessity (CMNS). These documentation requirements substantiate that the physician has reviewed the patient's condition and has determined that services or supplies are medically necessary.[3]

In March 2004, CMS Administrator Dr. Mark McClellan confirmed to the United States Senate that the CMN is the appropriate documentation to show that the beneficiary's need for the equipment is supportable:

> As a condition of coverage, CMS does require that the beneficiary's need for a wheelchair or power wheelchair is supportable. In fact, all claims for power wheelchairs must include a Certificate of Medical Necessity (CMN) which "certifies the need for the device and that it is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body part."[4]

INITIAL DETERMINATIONS

The interim rule, pursuant to Section 405.922, requires that a contractor issue initial determinations within 30 days for clean claims.[5] Failure to comply with the 30 day period will result in an interest payment to the individual awaiting such determination.

For non clean claims, the contractor must issue an initial determination within 45 days of receipt. The proposed rule does not provide for any interest payment should the determination extend beyond the 45 day time period.

Recommendation: We propose that the term "non clean" claim be defined so that Medicare participants will know when a claim will no longer be considered "clean." If a claim is paid at the QIC or ALJ level (or higher), such claims should be considered "clean" as a mistake was made by the carrier and interest should accrue from the date of the original denial. This would assure fairness and provide incentives to expedite claim determinations.

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[3] 64 Fed. Reg. 1813-1816 (Jan. 12, 1999) (emphasis added).

[4] Answers for the record to questions submitted by Senator John Kerry from the Senate Finance Committee Hearing on the nomination of Mark B. McClellan, to be Administrator of the Center for Medicare & Medicaid Services (March 8, 2004).

[5] The term "clean claim" is defined in Section 1842 of the Social Security Act as "a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment to prevent timely payments from being made on the claim.

REDETERMINATION

The proposed rule, pursuant to Section 405.966, requires that a party, "when filing a request for reconsideration" must "present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination... Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence."[6]

Recommendation: The requirement that parties submit all evidence prior to the redetermination decision places suppliers in a difficult position. We thus recommend that information obtained during the process is allowed to be submitted at any level. To deny the introduction of such evidence at any stage of the review process will have the impact of short-circuiting justice and denying a fair finding of fact if all relevant evidence is not allowed to be considered.

Parties must be afforded the opportunity to present new evidence at all levels of the appeals process. This is the only way to ensure true justice for all Medicare participants.

QUALIFIED INDEPENDENT CONTRACTOR LEVEL

On the Record Hearing

In order to meet statutory guidelines concerning time limits for appeals before Qualified Independent Contractors ("QIC"), CMS is proposing that all QIC appeals be "on the record." This would mean that Medicare participants would not have the opportunity to have a QIC determination in person or via telephone.

Recommendation: Medicare participants should have an opportunity to have a QIC hearing in person or via telephone. The opportunity to appear before a hearing officer or a QIC (in person or via telephone) is an important due process right for the provider/supplier and/or the beneficiary. Often times, Medicare beneficiaries participate in hearings with the supplier/provider and the opportunity of the hearing officer to witness the condition of the beneficiary is extremely important to the process. Further, Medicare participants should be allowed to present their case and address in person specific questions that might arise during the hearing.

Independence and Training of QIC's

The implementing legislation defines a QIC as "an entity or organization that is independent of any organization under contract with the Secretary." The legislation further provides that a QIC would have sufficient training and expertise in medical science and legal matters. Pursuant to Section 405.968 of the interim rule, QIC's "who

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[6] 70 Fed. Reg. 11481.

conduct reconsiderations must have sufficient medical, legal, and other expertise, including knowledge of the Medicare Program."[7]

Recommendation: The interim rule must set forth in greater detail the independence of the QIC and spell out in greater detail the specific legal expertise of the QIC. This being the case, we would propose that each QIC have a law degree or specific legal training (as well as a medical background) so that a complete understanding of the Social Security Act and the implementing regulations become part of any decision. Further, the proposed rule must clarify that any QIC (as well as anyone providing assistance to a QIC) be completely independent of the carrier and agency involved in this matter. Absent such language, we would contend that the interim rule does not comply with the intent of the implementing statute.

Further, will the QIC supercede the judgment of the patient's treating physician? If so, what would be the circumstances that justify such an override and when will Medicare participants not be able to rely on the treating physicians' expertise and paperwork? In the case of certain DME items, a supplier/beneficiary relies on the treating physician's certification contained in the CMN. In these cases, the appeals rule should outline the circumstances that would justify an override of the treating physician's completion of Medicare paperwork.

REOPENINGS

Section 405.980 of the interim rule provides that a contractor may reopen a claim(s) within 4 years from the date of the initial determination for good cause as defined in 405.986. Pursuant to 405.986, good cause may be established when (1) there is new and material evidence that was not available or known at the time of the determination or decision and may result in a different conclusion or (2) the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.[8]

Recommendation: The reopening of claims should be consistent with the concept of finality and fairness to the beneficiary, provider/supplier and the agency. Often times, the carrier seeks information that was readily available at the time of the original claim determination) and still claims that this meets the regulatory good cause standard. The carrier makes this claim even though it was at all times in complete control of the entire review process. It appears the carrier is arguing that its own internal system for review does not permit it to timely complete reviews or enable it to comply with federal regulations developed by CMS.

We think the current good cause standard should be enforced to ensure fairness and finality for those that participate in the Medicare program.

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[7] 70 Fed. Reg. 11481.
[8] 70 Fed. Reg. 11484.

ESCALATION

Time Frames

The proposed rule affords Medicare participants an opportunity to "escalate" to the next level of appeal should a decision not be rendered within the time frames outlined in the proposed rule.

Recommendation: We would recommend that time frames remain intact should a participant "escalate" to the next level. A participant should not lose his/her rights to an expedited hearing simply because a decision was not rendered at a lower level of appeal within the timeframe set forth in law. If decisions are not made within 45 days of a hearing, the Medicare participant should have an automatic right to escalate to the next level.

INDEPENDENCE AND FAIRNESS OF ALJs MUST BE ESTABLISHED AND MAINTAINED

Steps must be taken to ensure that ALJs maintain their independence as their oversight is transferred from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS). Specifically, the PMC is concerned that HHS training of ALJs will focus on more restrictive CMS policy or CMS program memoranda as opposed to federal statutes, regulations and case law.

Safeguards must be put in place to ensure that CMS cannot, through training or agency culture, attempt to influence the decisional independence of ALJs handling Medicare claims. At a minimum, HHS should ensure that:

- firewalls are put in place to ensure independence;
- procedures should be implemented for reporting and overseeing ALJ operations; and
- standards should be developed against which the independence of ALJs is measured.

We appreciate your time and consideration of these issues and look forward to working with HHS, CMS, and the power mobility community to address these concerns and ensure a fair and equitable Medicare appeals process.

Sincerely,

Eric W. Sokol
PMC Director

Stephen M. Azia
PMC Counsel

Submitter : Dr. JAMES H. SCULLY **Date:** 05/09/2005

Organization : THE AMERICAN PSYCHIATRIC ASSOCIATION

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

CMS-4064-IFC-24

Submitter : **Ms. Dawn Mancuso** **Date: 05/09/2005**

Organization : **Association of Air Medical Services (AAMS)**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4064-IFC-24-Attach-1.PDF

ASSOCIATION OF AIR MEDICAL SERVICES

May 9, 2005

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

Re: **Comments on CMS-4064-IFC—Medicare Claims Appeal Procedures**

Dear Sir or Madam:

The Association of Air Medical Services (AAMS) appreciates the opportunity to comment on the proposed regulation that would implement statutory changes to the Medicare claims appeal procedures. The Medicare claims appeals process plays a critical role in the daily operations of AAMS members whose case mix is heavily comprised of Medicare transports. We welcome changes that are designed to expedite the handling of appeals and provide additional assurances of fairness and independence in the process. We appreciate the time and effort that CMS has spent in developing the regulations to implement these important changes.

The Association of Air Medical Services' members represent about 90% of the air lift capacity in the United States and provide over 350,000 air medical transports each year. As Medicare air transports comprise up to 60% of annual operations for some AAMS members, AAMS is intent on making sure that members are given a fair opportunity to submit claims and receive reimbursement for medically necessary and appropriate transports. AAMS will therefore outline where it believes changes should be made in this interim final rule in order to allow a full airing of the facts surrounding each air medical claim appeal.

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Leading and Serving
Transport Medicine

FAILURE of "QIC" To Allow In-Person or Teleconference Participation Will Force Many More Appeals to Higher Level of Review. The interim final rule substitutes the "QIC" hearing for the Fair Hearing that has been traditionally been used at the second level of claims appeal. Those using the Fair Hearing process have always had the option of submitting an appeal in writing, appearing to argue the case in-person, or disposing of the appeal in a teleconference setting. The option of a "live" hearing procedure is the most effective method of assuring that all the facts known to the parties at that time are considered at this stage of appeal. Elimination of the "live" hearing option at the"QIC" level will reduce the number of cases resolved at this level thereby unfairly depriving or postponing air

medical programs' receipt of reimbursement dollars needed to carry out operations and maintain airframe and other assets in optimum condition.

Reconsiderations. Section 405.966(a)(2) of the rule, implementing section 1869(b)(3) of the statute, provides that if evidence is not submitted by a provider or supplier at the qualified independent contractor ("QIC") level, it cannot be submitted during a subsequent appeal without a finding of good cause. Air medical program operators are often unable to obtain a record or other documentation that may be necessary to prove their case at the reconsideration level. This is a particularly taxing matter for air medical programs in that they cover hundreds of miles of territory and work with several dozen hospitals, sometimes across state borders. As a result, an air medical program's ability to obtain written documentation from trauma center personnel is often very limited at the time of the event. In addition, lack of cooperation by a facility treating the patient or refusal of a physician to supply a letter documenting the order for an ambulance to be called, poses additional challenges to air programs as they attempt to obtain needed documentary evidence. The regulation needs to make clear that such occurrences, totally outside the supplier's control, would constitute good cause for such documentation to be considered at a subsequent appeal level whenever it might be obtained.

ALJ Hearings. Section 405.1010(d) provides that if CMS or a contractor participates in an ALJ hearing, they cannot be called as a witness. We do not understand the purpose of this provision or how it can lead to a more complete examination of all the issues, which we understand to be CMS' objective in allowing CMS or a contractor to participate in a hearing in the first place. It is frequently necessary for a supplier to call a contractor representative, or even CMS, as a witness in order to establish the grounds on which they based their action on a claim or determination. The fact that CMS or the contractor has been made party to the hearing is irrelevant to the usefulness of such testimony. CMS or its contractors should not be able to immunize themselves against being called as a witness simply by deciding to participate as a party to the hearing. We believe you should delete this provision of the rule.

Section 405.1036(f) allows subpoenas to be requested for an ALJ hearing, but states that they must be requested within 10 days of the notice of the hearing. Furthermore, a subpoena may be requested only after discovery is sought, a motion to compel is filed and granted, and the subpoenaed party does not supply the requested records. In light of the requirement that a party must exhaust these other efforts to obtain the records before seeking a subpoena, it is unreasonable to require that the request for a subpoena be filed within 10 days of the notice of hearing. The provision should be amended to require only that a subpoena request be filed before the decision of the ALJ. Alternatively, a party requesting a subpoena should be allowed a reasonable amount of time, after he has exhausted all other required efforts to obtain the records, to file the request for a subpoena.

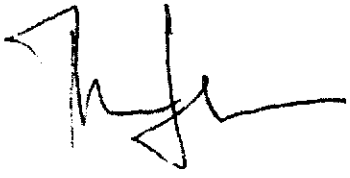
ALJ Hearing Should Once Again Be A "De Novo" Review of the Claim in Question.

ALJ hearings have been, prior to this interim final rule, de novo procedures, and therefore have provided the most effective forum for capturing relevant evidence of the appropriateness of the transports or treatment provided. AAMS believes that removal of "de novo" status for the ALJ process will hamper efforts to obtain the optimum amount of information about each case and will therefore lead to unfair and unjustified denials of legitimate Medicare claims for reimbursement. . The aforementioned removal of the "live" hearing option at earlier stages of the appeal process makes the continuation of the "de novo" status essential.

Conclusion. The above comments all reflect our overriding concern that the rules governing these appeals not erect unnecessary and unfair barriers to the presentation of a provider or supplier's case at the various hearing levels. The primary purpose of the rules should be to assure that a complete picture of the facts and circumstances is presented to the hearing officer and that the government or its agent should be required to the fullest extent to ensure that the record is complete. Unfortunately, as explained above, the rules set forth in the interim final regulation too often inject adversarial procedures and limitations on the collection and presentation of evidence that may stand in the way of developing a full and accurate record upon which a decision can be based. We urge you to examine these issues with a view toward what should be our common goal—adjudicating claims on the basis of a true and accurate set of facts.

We appreciate the opportunity to submit these comments. Please let us know if we can provide any additional information or assistance.

Very truly yours,



Thomas P. Judge, CCT-P
President

Dawn M. Mancuso, MAM, CAE
Executive Director/CEO

Submitter : **Date: 05/09/2005**

Organization :

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: CMS-4064-IFC - Changes to the Medicare Claims Appeals Procedures

Dear Dr. McClellan:

On behalf of the Association of American Physicians and Surgeons, a nonprofit group of thousands of physicians founded in 1943, we respectfully submit these comments on the Centers for Medicare and Medicaid Services ("CMS") interim final rule establishing new appeals procedures for Medicare Part A and Part B claims denials. See 70 Fed. Reg. 11420 (March 8, 2005) (the ?Interim Claims Appeals Rule.?) The Interim Claims Appeals Rule seeks to implement the changes in the Medicare appeals process contemplated by Congress in Section 931 of Subtitle D of Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173 (?MMA?) and the Medicare and Medicaid and Section 521 of the SCHIP Benefits Improvement Act of 2000, Pub. Law 106-554(?BIPA?).

We object to the proposal to give CMS policies greater deference than similar informal agency policies are typically granted within administrative appeal processes. ALJs currently decide whether informal agency policies are entitled to deference based on Supreme Court precedents. Many informal CMS policies, such as the much-criticized E&M Guidelines, can be used to deny Medicare claims, but these policies have not been promulgated in accordance with the notice-and-comment and Federal Register publication requirements of ?1811(b)(1) of the Social Security Act and ?553 of the Administrative Procedure Act currently.

Informal policies do not currently receive such special consideration as contemplated by the Interim Claims Appeal Rule. Rather, ALJs decide how much deference is due in a particular case based on the policy?s power to persuade. The Supreme Court has established factors to consider in determining the deference accorded to informal agency manuals: (1) the agency?s care and thoroughness in considering the policy (2) the agency?s consistency on the position, (3) the agency?s formality in reaching the policy, (4) the relative expertness of the agency, (5) the validity of the agency?s reasoning, (5) the formality of the policy, and (6) ?all those factors which give it power to persuade.? U.S. v Mead Corp., 533 U.S. 218, 228 (2001), citing Skidmore v. Swift & Co., 323 U.S. 134, 139-140 (1944).

We object to how the substantial deference standard incorporated in the Interim Claims Appeal Rule would essentially allow CMS to impose binding obligations on beneficiaries and providers without a public comment process. In order to establish the appearance and reality of a truly independent appeal process and a fair process for both sides in a Medicare dispute, ALJs and others must be able to review challenges to agency policies without a presumption of validity.

Thank you for your consideration of our comments.

AAPS
1601 N. Tucson Blvd. - Suite 9
Tucson, AZ 85716

Submitter : Dr. JAMES H. SCULLY **Date:** 05/09/2005

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT--PLEASE USE THIS VERSION--HAS EDIT CORRECTION.

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : **Mr. Daniel Pedersen** **Date: 05/09/2005**

Organization : **PAge, Wolfberg & Wirth**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

We would like to see the ability for a provider/ supplier to receive a notice of denial of payment (in addition to the beneficiary/ enrolee) for Part C (Medicare Advantage) related services be clarified. As the rules currently stand, it appears as though only the beneficiary receives a notice, and a provider/ supplier may not become aware of a denial, and may lose out on appeal rights, as well as reimbursement rights.

Submitter : Mr. William T. T. Hood **Date:** 05/09/2005

Organization : The SCOOTER Store

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

To: Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4064-IFC
P.O. Box 8011
Baltimore, MD 21244-8011

From: The SCOOTER Store
1650 Independence Drive
New Braunfels, TX 78132

May 9, 2005

RE: Comments to the Interim Final Rule Concerning Changes to the Medicare Appeals Process, CMS-4064-IFC

Dear Sir or Madam:

On behalf of The SCOOTER Store, a nationwide supplier of power mobility equipment headquartered in New Braunfels, Texas, we appreciate the opportunity to support already submitted comments in response to the changes to the Medicare Appeals Procedures that has been published as an interim final rule in 70 FR 11,420 (Tuesday, March 8, 2005).

The SCOOTER Store has long supported reforms to the Medicare Appeals Procedures that streamlines the process, provides statutorily finite timelines, respects the rights of beneficiaries and suppliers, and alleviates unnecessary administrative burdens on petitioners while maintaining balance, fairness, and justice in the system. To this end, The SCOOTER Store supports comments submitted by industry coalition, the Power Mobility Coalition (PMC). The PMC is a national association for manufacturers, suppliers, and beneficiaries of motorized scooters and power wheelchairs

The SCOOTER Store has had a productive dialogue with the government in the past, and we are committed to finding ways to improve the Medicare appeals process in order to better serve beneficiaries and American taxpayers. We look forward to continuing our open dialogue with CMS in the effort to provide clarity and consistency to this important benefit in the immediate future. CMS should continue to work with, and not against, industry leaders towards the goal of delivering mobility solutions to qualified Medicare beneficiaries.

Again, we thank you for the opportunity to submit this statement on this issue of great importance to seniors and the disabled

Sincerely,

William T. T. Hood, Jr.
Vice President of Operations for
Medicare/DMERC Relations and Policy

Submitter :

Date: 05/09/2005

Organization :

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

Resubmitting as an attachment.

CMS-4064-IFC-29-Attach-1.DOC

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: CMS-4064-IFC - Changes to the Medicare Claims Appeals Procedures

Dear Dr. McClellan:

On behalf of the Association of American Physicians and Surgeons, a nonprofit group of thousands of physicians founded in 1943, we respectfully submit these comments on the Centers for Medicare and Medicaid Services ("CMS") interim final rule establishing new appeals procedures for Medicare Part A and Part B claims denials. See 70 Fed. Reg. 11420 (March 8, 2005) (the "Interim Claims Appeals Rule.") The Interim Claims Appeals Rule seeks to implement the changes in the Medicare appeals process contemplated by Congress in Section 931 of Subtitle D of Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173 ("MMA") and the Medicare and Medicaid and Section 521 of the SCHIP Benefits Improvement Act of 2000, Pub. Law 106-554("BIPA").

We object to the proposal to give CMS policies greater deference than similar informal agency policies are typically granted within administrative appeal processes. ALJs currently decide whether informal agency policies are entitled to deference based on Supreme Court precedents. Many informal CMS policies, such as the much-criticized E&M Guidelines, can be used to deny Medicare claims, but these policies have not been promulgated in accordance with the notice-and-comment and Federal Register publication requirements of §1811(b)(1) of the Social Security Act and §553 of the Administrative Procedure Act currently.

Informal policies do not currently receive such special consideration as contemplated by the Interim Claims Appeal Rule. Rather, ALJs decide how much deference is due in a particular case based on the policy's power to persuade. The Supreme Court has established factors to consider in determining the deference accorded to informal agency manuals: (1) the agency's care and thoroughness in considering the policy (2) the agency's consistency on the position, (3) the agency's formality in reaching the policy, (4) the relative expertness of the agency, (5) the validity of the agency's reasoning, (5) the formality of the policy, and (6) "all those factors which give it power to persuade." U.S. v Mead Corp., 533 U.S. 218, 228 (2001), citing Skidmore v. Swift & Co., 323 U.S. 134, 139-140 (1944).

We object to how the substantial deference standard incorporated in the Interim Claims Appeal Rule would essentially allow CMS to impose binding obligations on beneficiaries and providers without a public comment process. In order to establish the appearance and reality of a truly independent appeal process and a fair process for both sides in a Medicare dispute, ALJs and others must be able to review challenges to agency policies without a presumption of validity.

Thank you for your consideration of our comments.

Association of American Physicians and Surgeons
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